

EXHIBIT A

1 UNITED STATES DISTRICT COURT
2 CENTRAL DISTRICT OF CALIFORNIA
3 EASTERN DIVISION-RIVERSIDE

4 HONORABLE VIRGINIA A. PHILLIPS, JUDGE PRESIDING

5 G. DAVID JANG, M.D.,)

6 Plaintiff,)

7 V.)

DOCKET NO. EDCV 05-426 VAP

8 BOSTON SCIENTIFIC CORPORATION,)
9 et al.,)

10 Defendants.)

11 REPORTER'S TRANSCRIPT OF ORAL PROCEEDINGS
12 Riverside, California
13 Tuesday, May 30, 2006

14 PHYLLIS A. PRESTON, CSR
15 License No. 8701
16 Official Court Reporter
17 United States District Court
18 3470 Twelfth Street
19 Riverside, California 92501
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COPY

APPEARANCES

For the Plaintiff:

GIBSON, DUNN & CRUTCHER LLP
By: WAYNE BARSKY, JULIAN POON,
JUNE TAI & BRENDA KLEIDOSTY
333 South Grand Avenue
Los Angeles, California 90071-3197
and
MUNDELL, ODLUM & HAWS
By: THOMAS MUNDELL
650 E. Hospitality Lane, Suite 470
San Bernardino, California 92408

For the Defendants:

HOWREY LLP
By: MATTHEW WOLF, EDWARD HAN &
JOHN NILSSON
1299 Pennsylvania Avenue, NW
Washington, DC 20004

1 problems with that. It wasn't very flexible. So what
2 happened? Let's go to the next slide.

3 Dr. Palmaz came out with a new patent. Now, I
4 believe Mr. Barsky misspoke when he said that it was Dr. Jang
5 that thought of connectors, because, in fact, there were
6 connectors throughout the prior art long before Dr. Jang's
7 patents were filed. And one of them is shown here. We can
8 see in red the expansion segments and then in blue the
9 connecting segments, the connecting struts.

10 These then were taken forward in various
11 permutations. In the upper left we see the Pinchasik, in the
12 bottom we see Orth, in the upper right we see Fischell.
13 These are all prior art stents. Lots of different shapes but
14 they were all made of the same basic components. At least
15 certainly with Fischell and Orth you had expansion struts and
16 connector struts. These were the building blocks of stents.

17 Against this crowded prior art backdrop Dr. Jang
18 brought forward his invention. And let's talk about his
19 invention. First, we have expansion struts. They are
20 attached circumferentially by joining struts which are called
21 expansion strut pairs when the two struts are put together
22 with a joining strut. There are then connecting struts. And
23 these connecting struts -- here is the invention of
24 Dr. Jang's patent. The connecting struts allow the expansion
25 strut pairs to be circumferentially offset. If you look at

EXHIBIT B

REDACTED

EXHIBIT C

REDACTED

EXHIBIT D

REDACTED

EXHIBIT E

- VOLUME E -

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION, : CIVIL ACTION

Plaintiff :

vs. :

CORDIS CORPORATION and :
JOHNSON & JOHNSON, INC., :

Defendants : NO. 03-27 (SLR)

BOSTON SCIENTIFIC SCIMED, INC., : CIVIL ACTION
and BOSTON SCIENTIFIC :
CORPORATION, :

Plaintiffs :

vs. :

CORDIS CORPORATION and :
JOHNSON & JOHNSON, INC., :

Defendants : NO. 03-283 (SLR)

Wilmington, Delaware
Tuesday, June 28, 2005
9:28 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Valerie J. Gunning and
Leonard A. Dibbs,
Official Court Reporters

1 Q. Would a stent designer of ordinary skill in 1996
2 have had any motivation at all to try to mix and match
3 and combine any of these elements from any of these
4 patents to arrive at the claimed invention with these
5 elements of Claim 36?

6 A. No. As I said, this patent, for example, teaches
7 away. These -- there's no way these four patents could
8 be combined to arrive at Dr. Jang's invention because
9 they teach away from each other. One thing teaches one
10 thing. Another patent teaches another. And, really,
11 there would be no motivation to combine things that are
12 telling you to do two completely different things.

13 Q. Now, Doctor, Cordis had some other references.
14 Did you kind of group these together on one slide,
15 BSE-4248?

16 A. Yes.

17 Q. So let's go ahead and take a look, please.
18 BSE-4248.

19 What do we see here, Doctor?

20 A. Here we see some of the other things that Cordis
21 is calling prior art. And we see a sort of hoop
22 arrangement here (indicating) that's connected with this
23 undulating longitudinal member here and clearly, this
24 kind of undulating longitudinal member could never be
25 used to have offset connectors. It's not described in

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2 Q. Okay. So let's look at Figure 1. And the Hess
3 application also shows two expansion columns; right?

4 A. Figure 1 there; is that right?

5 Q. This is Figure 1. I'm blowing it up so we can look
6 at it better.

7 A. Okay.

8 Q. Is that true?

9 A. Yes.

10 Q. Okay. Color the expansion columns.

11 And also shows top to bottom connectors;
12 right?

13 A. Right. Not bottom to top.

14 Q. No, not bottom to top. That would be a very
15 different invention, wouldn't it?

16 A. Perhaps.

17 Q. Perhaps? Let's look below Figure 1 in Hess, an
18 expanded version. That's Figure 2; right? No, no, no.

19 MR. DISKANT: May I see the page? Let's look
20 at the whole page.

21 Let me just go to the Elmo.

22 BY MR. DISKANT:

23 Q. Okay. Figure 2 is expanded Figure 1; right? At
24 least that's what Hess calls it.

25 A. It doesn't look to be entirely accurate.

EXHIBIT F

REDACTED

EXHIBIT G



US005449373A

United States Patent [19]

Pinchasik et al.

[11] Patent Number: 5,449,373

[45] Date of Patent: Sep. 12, 1995

[54] **ARTICULATED STENT**[75] Inventors: Gregory Pinchasik; Jacob Richter,
both of Ramat Hasharon, Israel[73] Assignee: Medinol Ltd., Ramat Hasharon,
Israel

[21] Appl. No.: 213,272

[22] Filed: Mar. 17, 1994

[51] Int. Cl.⁶ A61M 5/00; A61F 2/02[52] U.S. Cl. 606/198; 623/1;
623/12[58] Field of Search 623/1, 11, 12; 606/108,
606/191-195, 198, 200; 604/8[56] **References Cited****U.S. PATENT DOCUMENTS**

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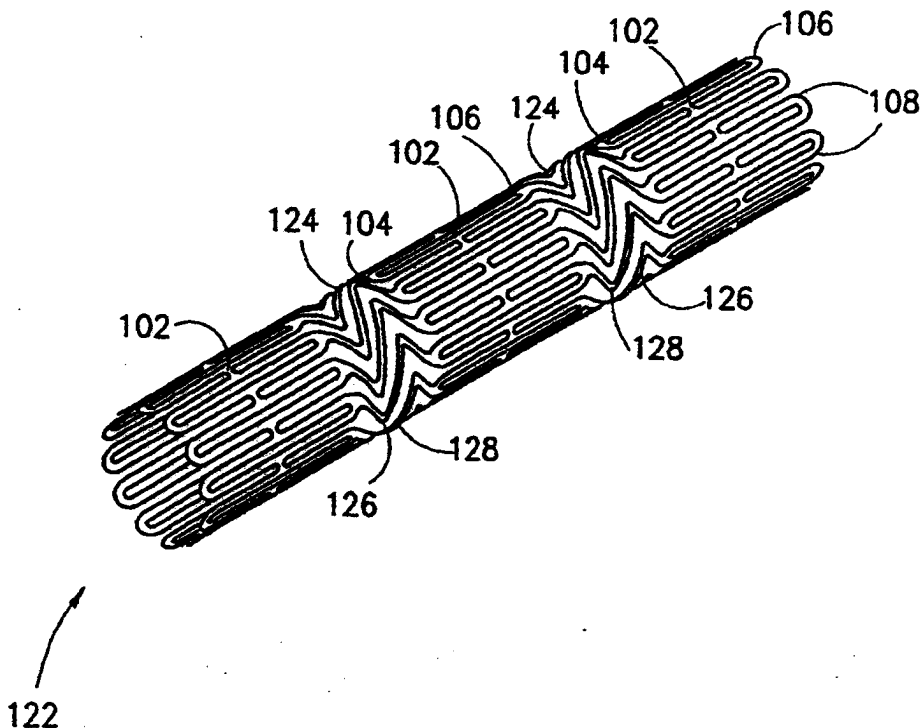
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Primary Examiner—Stephen C. Pellegrino*Assistant Examiner*—William Lewis*Attorney, Agent, or Firm*—Skjerven, Morrill,
MacPherson, Franklin & Friel[57] **ABSTRACT**

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

6 Claims, 5 Drawing Sheets



U.S. Patent

Sep. 12, 1995

Sheet 1 of 5

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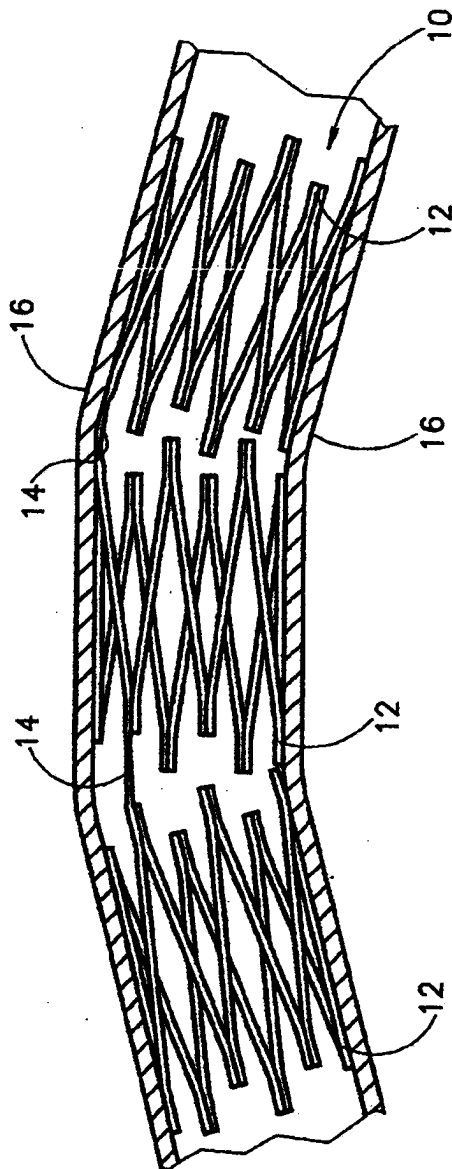


FIG. 1
PRIOR ART

U.S. Patent

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FIG. 2A

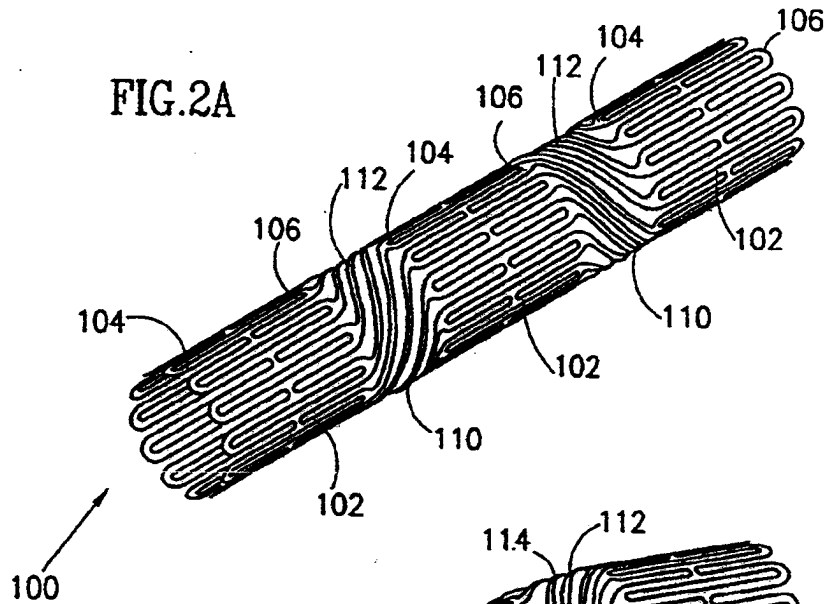


FIG. 2B

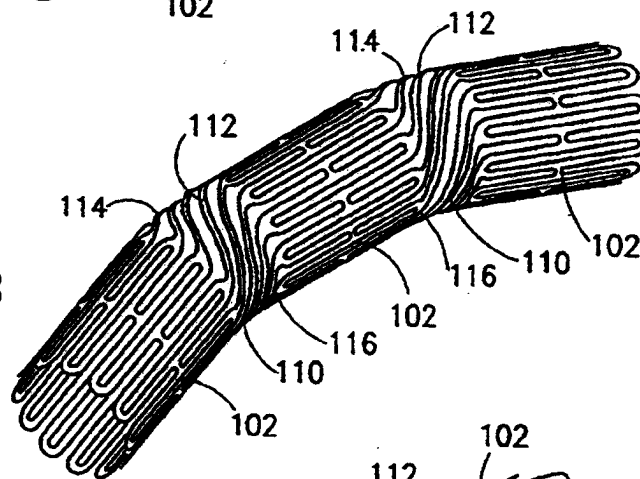
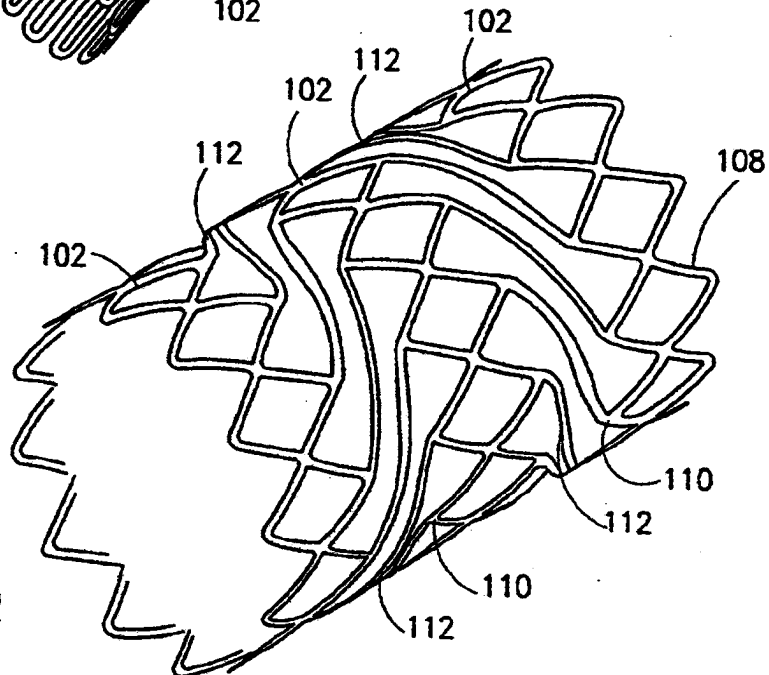


FIG. 2C

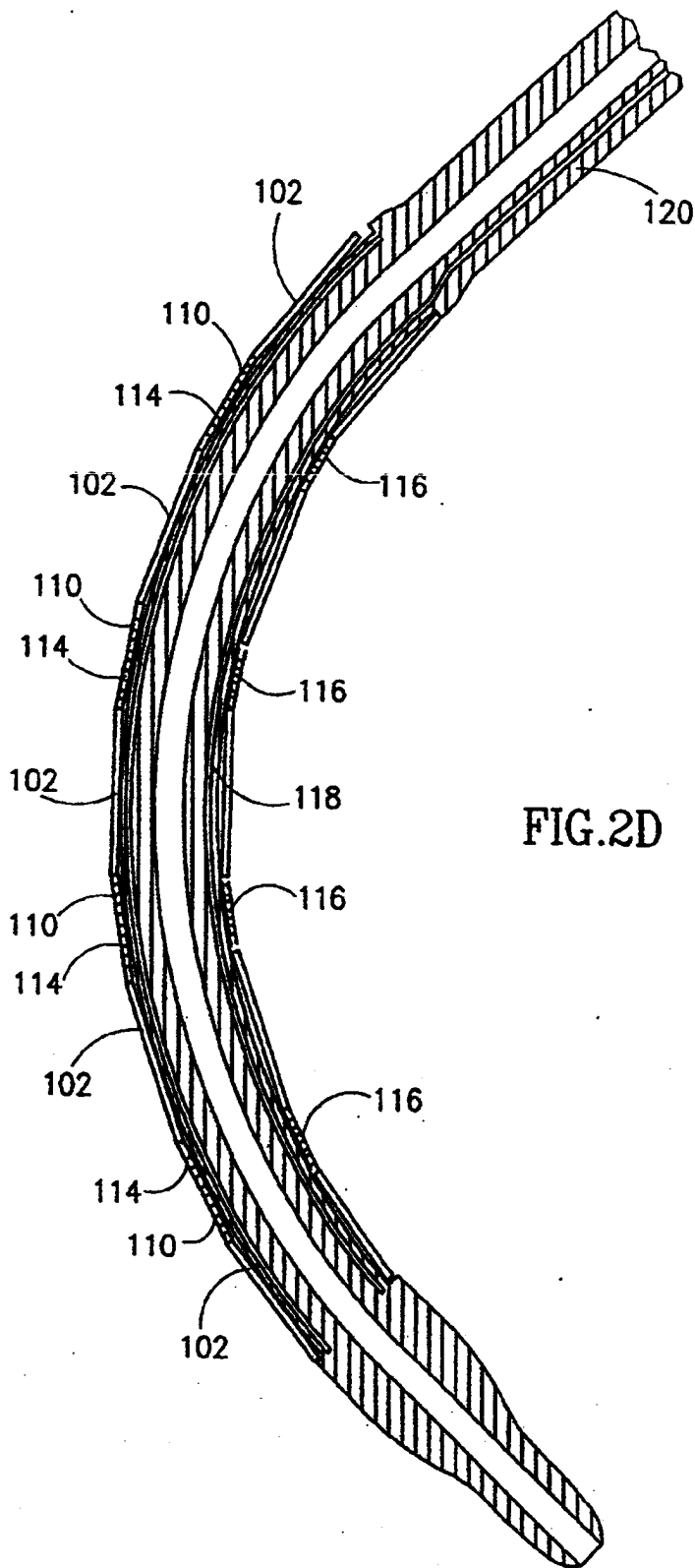


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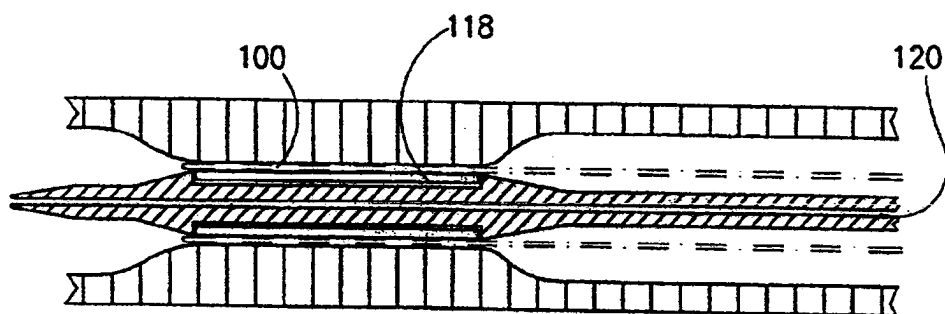


FIG. 2E

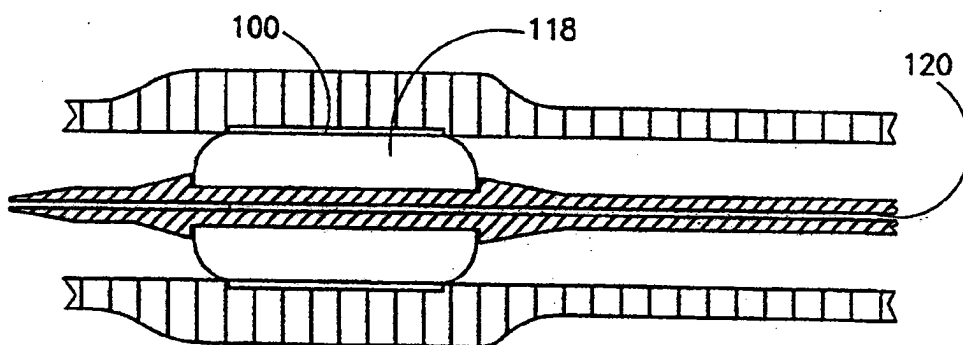


FIG. 2F

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FIG. 3A

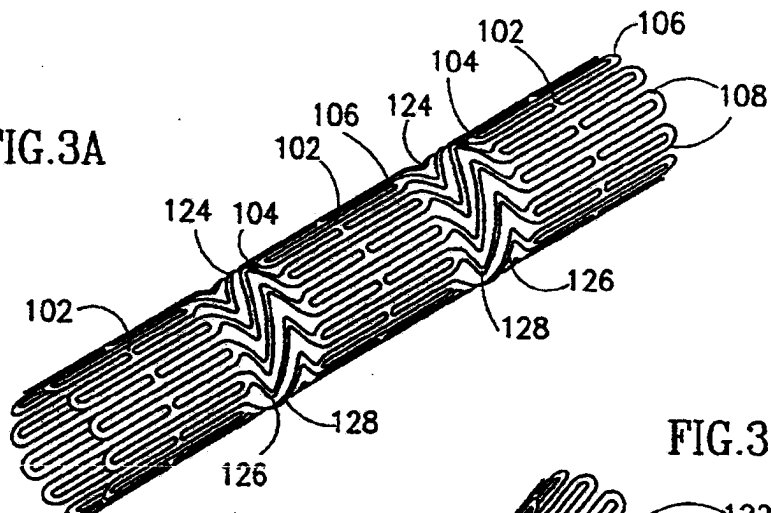


FIG. 3B

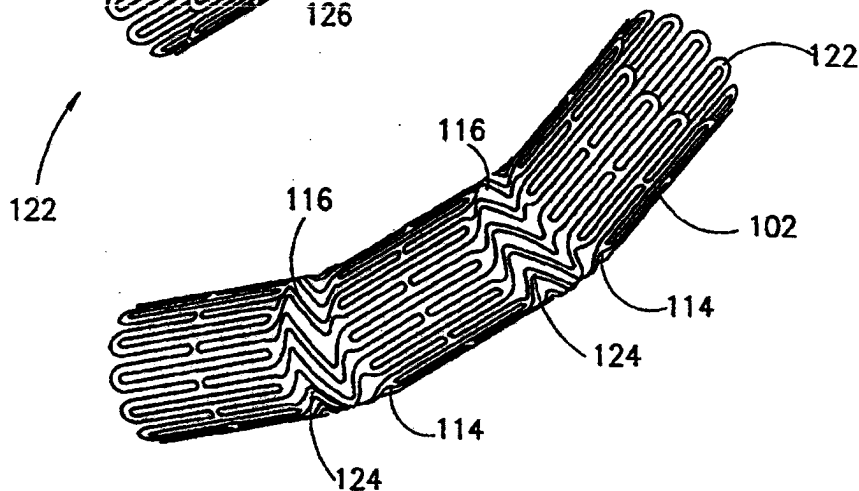
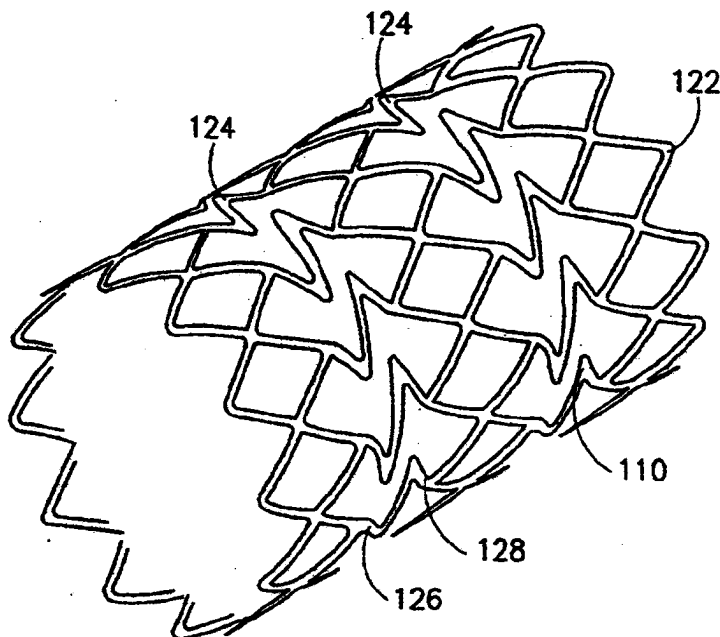


FIG. 3C



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ARTICULATED STENT

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent 10 deployed in a curved blood vessel 16 is now described with reference to FIG. 1 which is, in actual fact, FIG. 2 of the above referenced U.S. Pat. No. 5,104,404. Stent 10 is made up of a number of individual segments 12 articulated by hinges 14 connected at each end to segments 12. Stent 10 is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S. Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now be described.

The delivery of stent 10 through curved blood vessel 16 is more complicated than the delivery of a non-articulated stent in that stent 10 has to be angularly oriented such that its hinges 14 are located towards the convex portion of blood vessel 16 so that stent 10 can be flexed inward. In the present example, it will be noted that hinges 14 are located on the same side of segments 12 because blood vessel 16 has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel 16, stents 10 are shown to be lacking in that the gaps between segments 12 render the curved portion of blood vessel 16 without support. Furthermore, the gaps at the convex portion of blood vessel 16 are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel 16.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

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It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8-24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9-21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. 2a and 2b show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. 2c shows the expanded stent of FIG. 2 after plastic deformation;

FIG. 2d shows the stent of FIG. 2 mounted on a catheter in its flexed state;

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FIGS. 2e and 2f show the stent of FIG. 2 before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. 3a and 3b show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3c shows the expanded stent of FIG. 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. 2a-2c show an articulated stent, generally designated 100, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments 102 connected by connectors 110.

Segments 102 are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells 108 having 1 mm sides on expansion as best seen in FIG. 2c. Depending on the intended diameter of stent 100, segments 102 typically comprise between 8-24 diamond shaped cells 108.

Connectors 110 comprise links 112 connecting a front end 104 to a tail end 106 of adjacent segments 102. Links 112 preferably extend in a substantially helical fashion between apexes of diamond shaped cells 108 at front and rear ends 104 and 106 of adjacent segments 102 such that the number of links 112 equals the number of cells 108. Links 112 are preferably evenly deployed around perimeters of segments 102 such that connectors 110 can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors 110 at front and rear ends 104 and 106, respectively, of a segment 102 preferably have links 112 wound in clockwise and counter clockwise directions. Alternately winding connectors 110 ensures that the rotational displacement of links 112 and adjacent segments 102 relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent 100 is expanded.

It is particular feature of the present invention that connectors 110 have a generally cylindrical configuration when stent 100 is relaxed as best seen in FIG. 2a and a differentially stretched and compressed curved configuration when stent 100 is flexed as best seen in FIG. 2b. The flexed configuration is brought about by two relatively opposing displacements of links 112. First, the differential stretching of connectors 110 occurs at the convex portion thereof denoted 114 by links 112 being displaced away from one another. Second, the differential compressing of connectors 110 occurs at the concave portion thereof denoted 116 by links 112 being displaced towards one another.

Stent 100 has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 2a and 2b and an expanded diameter as shown in FIG. 2c for supporting a bodily conduit. Stent 100 is preferably

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fabricated from low memory, more plastic than elastic, bio-compatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent 100 typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively.

With reference now to FIGS. 2d-2f, stent 100 is shown overlying a balloon 118 forming part of its catheter delivery system 120. Stent 100 is mounted on its catheter delivery system 120 in its constricted diameter state shown in FIG. 2e for plastic deformation through inflation of balloon 118 to its expanded diameter shown in FIG. 2f for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments 102 connected by four 1 mm long connectors 110 and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent 100 is considerably simpler than the delivery of prior art articulated stent 10 because stent 100 is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent 100 over prior art stents 10, that stent 100 provides continuous and uniform support along the entire length of a blood vessel by means of segments 102 and unflexed connectors 110 supporting straight portions thereof while connector portions 114 and 116 supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. 3a and 3b, an articulated stent 122 is shown in which connectors 124 comprise links 126 having one or more kinks 128. The design of connectors 124 is preferred to that of connector 110 because stent 100 may have a tendency to rupture balloon 118 due to two reasons. First, links 112 overlying the convex portion of balloon 118 have a tendency to be biased inward when stent 100 is flexed. Second, segments 102 display a rotational displacement relative to balloon 118 when stent 100 is expanded.

In this case, the differentially stretched and compressed curved configuration of connector 124 is brought about by two relatively opposing displacements of links 126 as before except that the differential stretching of connectors 124 at convex portion 114 occurs by kinks 128 being somewhat straightened out while the differential compressing of connectors 124 at concave portion 116 occurs by kinks 128 being more acutely bent.

In a similar fashion to stent 100, stent 122 has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 3a and 3b and an expanded diameter as shown in FIG. 3c for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An articulated stent, comprising:

(a) at least two substantially rigid segments having a plurality of connected cells each having apices, wherein, upon expansion, each of said rigid seg-

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ments presents a substantially cylindrical diamond mesh; and
 (b) a flexible connector, comprising a plurality of flexible links wherein each of said flexible links connects apices of adjacent cells on adjacent rigid segments; each of said flexible links includes a plurality of portion with each pair of neighboring portions having an area of inflection therebetween, and during expansion of said stent, said area of inflection remains inflected.

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2. The stent as in claim 1, wherein said plurality of links includes between 8-24 links.

3. The stent as in claim 1 made from bio-compatible material capable of a more plastic than elastic deformation.

4. The stent as in claim 3, wherein said material is stainless steel.

5. The stent as in claim 3, wherein said material is gold.

6. The stent as in claim 3, wherein said material is tantalum.

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EXHIBIT H



US005545210A

United States Patent [19]

Hess et al.

[11] **Patent Number:** 5,545,210[45] **Date of Patent:** Aug. 13, 1996[54] **METHOD OF IMPLANTING A PERMANENT SHAPE MEMORY ALLOY STENT**

[75] Inventors: Robert L. Hess, Portola Valley; John E. Bramfitt, Woodside, both of Calif.

[73] Assignee: Advanced Coronary Technology, Inc., Menlo Park, Calif.

[21] Appl. No.: 310,100

[22] Filed: Sep. 22, 1994

[51] Int. Cl.⁶ A61F 2/06

[52] U.S. Cl. 623/1; 623/11; 623/12; 606/198

[58] Field of Search 606/191, 194, 606/195, 198; 623/1, 12; 604/281

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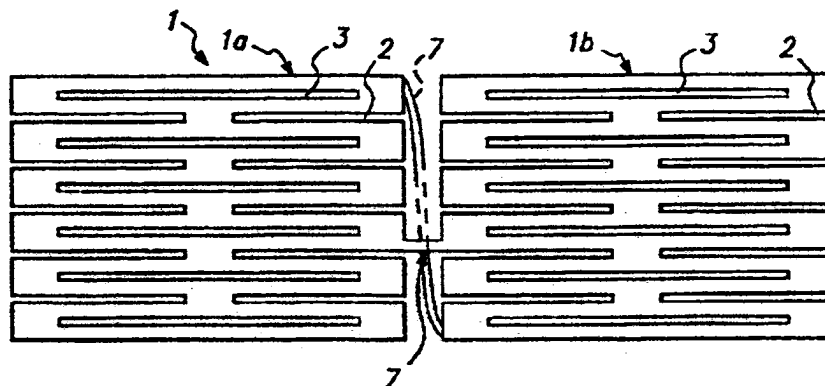
Primary Examiner—Gary Jackson

Assistant Examiner—Patrick W. Rasche

Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis, L.L.P.

[57] **ABSTRACT**

A permanent tissue supporting device, and a method for supporting tissue, wherein a stent-like member comprising a shape-memory alloy is permanently positioned to support the tissue of a tubular organ of a living body. The shape-memory alloy of the positioned stent-like member is in the martensitic state and exhibits a strain on a horizontal plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the tubular organ.

7 Claims, 1 Drawing Sheet

5,545,210

Page 2

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Aug. 13, 1996

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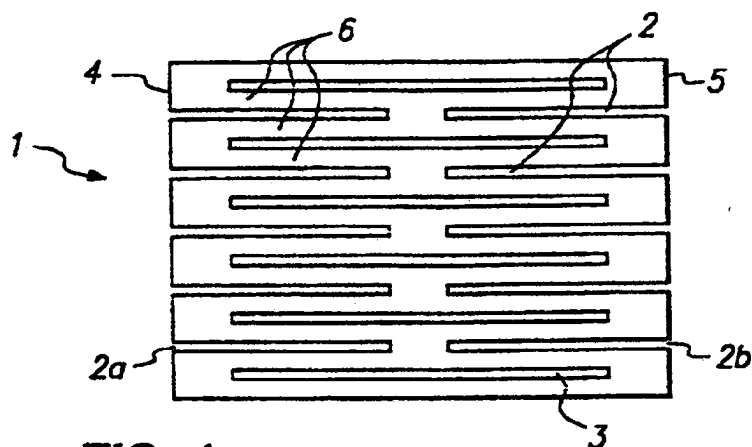


FIG. 1

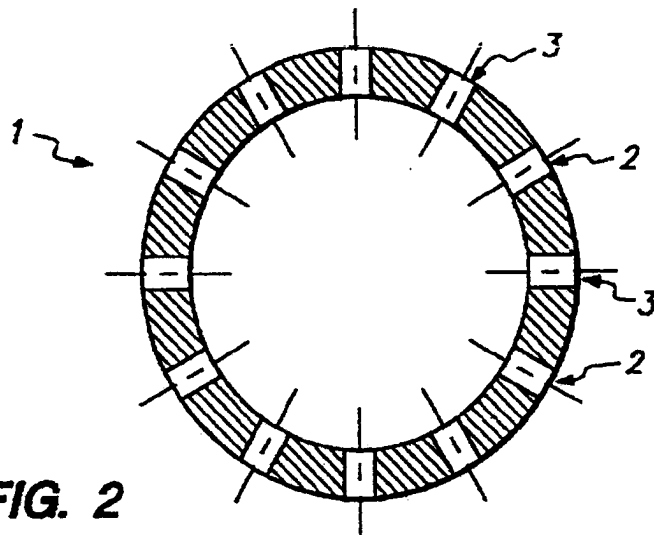


FIG. 2

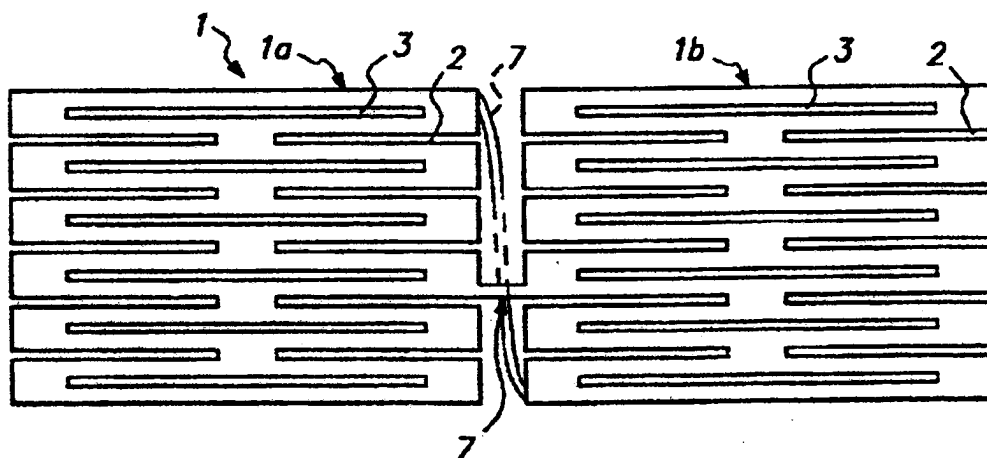


FIG. 3

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METHOD OF IMPLANTING A PERMANENT SHAPE MEMORY ALLOY STENT

FIELD OF THE INVENTION

The invention relates to tissue supporting devices (stents), preferably vascular stents for reputing blood vessels, and more particularly, to non-removable devices which will permanently support a dilated stenosis of a tubular organ (hollow viscus) such as a blood vessel.

BACKGROUND OF THE INVENTION

In the past, permanent or biodegradable devices have been developed for implantation within a body passageway to maintain vascular patency. These devices are typically characterized by the ability of such an intravascular device to be enlarged radially after having been introduced percutaneously, to be transported transluminally, and to be positioned in a desired location. These devices are either expanded mechanically, such as by the expansion of a mandrel positioned inside the device, or are capable of releasing stored energy to expand themselves upon actuation within the body.

U.S. Pat. Nos. 4,739,762, 4,776,337 and 4,733,665 disclose expandable and deformable intraluminal vascular grafts in the form of thin-walled tubular members which are expanded radially outwardly into contact with a body passageway, the members being plastically deformed beyond their elastic limit and the members being permanently fixed within the body. Suitable materials for the fabrication of these tubular-shaped members would include silver, tantalum, stainless steel, gold, titanium, or other suitable plastically deformable materials which may be permanently deformed. Permanent deformation is achieved when the material is subjected to a force which creates a strain greater than the elastic limit of the material which is utilized to make the tubular member. The open-mesh configuration of such devices is soon encapsulated by body tissue and cannot be removed. The exceeding of the elastic limit of the material used in such devices is also believed to compromise the performance of the devices in situ.

U.S. Pat. No. 4,969,458 discloses a vascular stent formed from a wire component made of material, such as copper alloy, titanium, or gold, wherein the wound configuration unwinds upon expansion and becomes a permanent prosthesis stent, similar to prior art devices disclosed above, and is not removable.

U.S. Pat. No. 4,969,890 discloses various configurations of shape-memory alloy members which have been previously radially compressed and which, upon positioning within the body and thermal activation, expand by themselves to become a permanent prosthesis within the body. In this regard, the reference teaches a device which operates in a similar fashion to the device disclosed in U.S. Pat. No. 4,485,816. U.S. Pat. No. 4,485,816 discloses a shape-memory alloy staple which, when heated, penetrates and cinches tissue together. Shape-memory alloy historically has been used to perform work in such a fashion wherein the component remains in a strong austenitic state after temperature activation. That is, above its transition temperature from marten site to austenite, and as the references above disclose, the shape-memory alloy either dilates an incompetent blood vessel or holds segments of tissue together. Neither of these devices is practically removable by a method which does not require surgery.

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Shape-memory alloys possess the useful characteristic of being capable of changing physical dimensions upon heating above a first transition temperature, A_s , between a soft martensitic metallurgical state and a hard austenitic metallurgical state of the alloys. A shape-memory alloy member can be processed while in a high temperature austenitic phase to take on a first configuration. After cooling the shape-memory alloy member below a second transition temperature M_s between the austenitic and martensitic states without change of physical dimensions, the shape-memory alloy member can be mechanically deformed into a second configuration. The shape-memory alloy member will remain in this second configuration until further heating to a temperature above A_s at which time the shape-memory alloy member will revert to its first configuration. A shape-memory alloy member can exert large forces on adjacent members during the transition from the second configuration to the first configuration. Numerous inventions have taken advantage of shape-memory alloy members capable of exerting this thermally activated force.

Shape-memory alloys have the further useful characteristic that, in the martensitic phase, the stress-strain curve exhibits a plateau indicating that a limited increase in strain can be achieved with imperceptible increase in stress. This martensitic stress-strain plateau usually defines the range of mechanical strain which can be recovered by the application of heat. Exceeding the upper end of this strain range may result in non-heat recoverable deformation.

U.S. Pat. No. 5,197,978, hereby incorporated by reference, discloses shape-memory alloy tissue supporting devices that are made to expand or shrink radially upon mechanical or thermal actuation, and, in particular, devices that are removable from the body.

It would be advantageous to have a tissue supporting device of a generally tubular configuration which can be inserted into a body duct or cavity while in an unexpanded shape and then be expanded to provide permanent support for the tissue forming the duct or cavity, such that the device when expanded does not exert a radial load on the supported duct or cavity and where the device when expanded has sufficient crush resistance to provide support for the duct or cavity when the duct or cavity exerts a normal radial compressive load on the device as the result of major contractions of the tissue.

It would be further advantageous to have a tissue supporting device, for simultaneous support of cavities of different sizes, in which larger expanded device sizes do not require higher expansion pressures than smaller device sizes, so that the potential for dissection and/or tissue damage is minimized, and where further the device remains somewhat flexible to accommodate movement of soft tissue.

It would be further advantageous to have a heat-to-expand tissue supporting device that does not need to be cooled prior to installation and which provides permanent tissue support while in the martensite state during service.

It would be further advantageous to have a method for reversibly manipulating the configuration of a device designed for tissue support, in order to facilitate machining, deburring, etc. of hard-to-reach interior surfaces of the device without affecting the functionality of the device in a final product.

SUMMARY OF THE INVENTION

The invention provides a tissue supporting device comprising a stent-like member of a shape-memory alloy which

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transforms from a martensitic metallurgical state to an austenitic metallurgical state when heated above a first transition temperature A_f and transforms from the austenitic state to the martensitic state when cooled below a second transition temperature M_f . The stent-like member is mechanically deformable without plastic deformation in a body passage of a living person from a first configuration while in the martensitic state to a second configuration in the martensitic state and the A_f and M_f transition temperatures are sufficiently above a body temperature of the living person to prevent recovery of the stent-like member to the first configuration by heating the stent-like member above A_f without permanently damaging surrounding tissue of the living person, the stent-like member exhibiting a strain on a horizontal plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the tubular organ.

The stent-like member can have various features. For instance, the stent-like member can have a tubular shape with a plurality of slots, each of the slots extending parallel to a central axis of the stent-like member. The slots can be rectangular in shape and ends of the slots circumferentially adjacent to each other can be offset in an axial direction. The slots can form a uniform pattern with at least two axially spaced-apart slots aligned with each other at locations spaced circumferentially around the stent-like member. In the expanded condition, the stent like member can have an essentially cylindrical, mesh-like shape which inhibits thrombosis when expanded in an artery of a living person. The stent-like member can include struts and the stent-like member can be radially expanded to an expanded configuration wherein the stent-like member has a planar cylindrical profile and the struts are not twisted such that edges thereof project radially outwardly. The shape-memory alloy is preferably an alloy of Ni and Ti having an $A_f \geq 62^\circ \text{C}$. The stent-like member can include at least one hinge-like member extending between adjacent sections of the stent-like member. The hinge-like member can be formed integral with the sections of the stent-like member and the hinge-like member can have an axial length shorter than an axial length of each section of the stent-like member. The hinge-like member can comprise a single axially extending strip of the shape-memory alloy.

The invention also provides a method of implanting a tissue supporting device comprising a stent-like member of a shape-memory alloy having martensitic and austenitic metallurgical states and a transition temperature A_f therebetween. The method includes mechanically expanding the stent-like member in its martensitic state followed by heating the expanded stent-like member above A_f and further expanding the stent-like member after which the stent-like member is cooled to body temperature. The A_f temperature can be above 37°C . and below 62°C ., for instance 40°C to 50°C . and the alloy can be a NiTi alloy. The method can further include crimping the tissue supporting device onto a balloon located at a distal end of a catheter and navigating the tissue supporting device to an application site within the tubular organ. The expanding step can be carried out by mechanically expanding the tissue supporting device until the balloon is fully inflated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a side view of a tissue supporting device in accordance with the invention;

FIG. 2 shows a cross-sectional view of a tissue supporting device in accordance with the invention; and

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FIG. 3 shows a tissue supporting device in accordance with the invention comprising two tissue supporting elements joined by a bridging system.

DETAILED DESCRIPTION OF THE INVENTION

According to the invention, a tissue supporting device is provided which can be inserted into a body passage, such as a blood vessel, duct or cavity, and used to support the tissue forming the duct or cavity. In particular, a tissue supporting device comprising a material which exhibits a stress-strain curve wherein an increase in strain can be achieved with a negligible increase in stress. The tissue supporting device is of generally tubular shape is provided which can be inserted into a body duct or cavity in an unexpanded shape and then be expanded at a desired position in the duct or cavity to form a permanent supporting structure for the tissue surrounding the expanded device.

The tissue supporting device can be fabricated from a shape memory alloy such as a binary Ni-Ti alloy or NiTi alloy having one or more additional elements added thereto. Other possibilities include shape memory alloys from the Cu-Al-Ni system. Such alloys have martensitic and austenitic metallurgical states and a transition temperature therebetween. The shape-memory alloy according to the invention is characterized by a stress/strain curve in the martensitic state wherein a limited increase in strain can be achieved with imperceptible increase in stress.

A tissue supporting device according to the invention can be made from a Ni-Ti alloy whose tensile strength in the martensitic state at human body temperature is 8 to 25 ksi. According to one embodiment of the invention, the transition temperature at which the alloy transforms from the martensitic to the austenitic state is preferably at a temperature of 70°C . or higher. At such temperatures, known thermal recovery techniques for shrinking shape memory alloy tubular devices can not be used to recover the tissue supporting device without causing permanent damage to surrounding tissue or blood due to thermal trauma which has been found to occur when tissue/blood is exposed to temperatures above 62°C .

A first embodiment of a tissue supporting device 1 in accordance with the invention is shown in FIGS. 1 and 2. As shown in the side view of FIG. 1, the device 1 includes a plurality of rectilinear slots 2, 3. Slots 2 are arranged in axially aligned pairs such that a first slot 2a intersects one axial end 4 of the device 1 and the other slot 2b intersects the other axial end 5 of the device 1. Slots 3 are arranged such that circumferentially adjacent slots 3 are separated by a pair of the aligned slots 2. Further, a single slot 3 is located between axial ends 4, 5. As shown in FIG. 2, slots 2, 3 are distributed in a uniform pattern around the devices. When the device 1 is expanded by inflating a balloon of a balloon catheter, legs 6 extending between axial ends of slots 2, 3 are mechanically deformed such that they are no longer parallel to the center axis of device 1.

FIG. 3 shows a device 1 comprising first and second sections 1a, 1b joined by bridging member 7. The bridging member can have any suitable configuration such as a straight, helical (shown in phantom in FIG. 3) curved or wavy strip. If desired, any number of sections of device 1 could be interconnected by bridging members 7. Also, adjacent sections of device 1 can be connected by a plurality of bridging members which are spaced apart and distributed at different locations around the circumference of the stent.

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The arrangement shown in FIG. 3 is advantageous for negotiating tortuous body cavities such as blood vessels having sharply angled bends therein and for expanding sections 1a, 1b to different diameters.

The stent-like member 1 according to the claimed invention, when fabricated from a Ni-Ti shape-memory alloy, can be expanded in a blood vessel to a range of desired sizes by inflating a balloon catheter to a pressure of 4-10, preferably 6-8 atmospheres of pressure in the balloon catheter. When the stent is expanded, the slots are enlarged into generally diamond shaped rectangular openings arranged in a uniform pattern that is in the form of a mesh-like lattice. In the embodiment shown in FIG. 3, expansion of the individual stent-like members 1a, 1b can be performed separately to achieve different diameters. Due to the expansion in the martensitic condition, stent-like members expanded to larger sizes do not require higher expansion pressures than stent-like members expanded to smaller sizes provided that the tissue supporting device comprises stent-like members made from the same generally tubular shape-memory alloy material. This embodiment offers the advantage of minimizing the potential for dissection and/or tissue damage.

The stent-like member 1 can be positioned at its application site in a low profile configuration with radial dimensions small enough to allow navigation of orifice and ducts leading to the site of application. The stent-like member 1 can be positioned by means of a balloon catheter device having a lumen portion, balloon portion, and guide portion with the stent-like member 1 surrounding the balloon portion. In a preferred embodiment, stent-like member 1 is mechanically crimped securely to the balloon portion prior to insertion of the balloon catheter device in a blood vessel.

In use, the balloon portion is expanded, thus deforming stent-like member 1 radially outward against an inner wall of a blood vessel, and forming a supporting structure for the blood vessel. The expansion of the stent-like member according to the invention takes place in the elastic region of the stress-strain curve defined by the horizontal plateau in that curve. The deformed stent-like member 1 can comprise the tubular shape shown in FIGS. 1-3 or any other suitable shape which can be mechanically deformed without permanently deforming the device. The stent is designed so that the strain in the expanded stent-like member 1 is controlled such as by slot length of the slots 2, 3. Use of a shape memory NiTi alloy for the device is advantageous since such material can exhibit anti-thrombotic properties.

Once the balloon catheter has been removed by collapsing the balloon portion, stent-like member 1 is left implanted to permanently support the blood vessel. The overall geometry of the stent-like member 1 ensures that the snapback at expansion is minimized and is proportional to the expanded size of the stent-like member 1. Since the implanted stent-like member exhibits a strain on a horizontal plateau on a stress-strain curve for the shape-memory alloy, the stent-like member can support the blood vessel at essentially constant stress. The expanded dimensions of the stent-like member 1 cannot be adjusted by the amount of force used to expand the device. Instead, the expanded diameter is controlled by the dimensions of the duct, cavity or, blood vessel, into which the stent-like member 1 is expanded. According to the invention, the shape memory alloy of the stent-like member 1 remains in the martensitic state when the stent-like member 1 is in service in a human body.

The duct supportive properties of an implanted member can be controlled by the wall thickness of shape-memory alloy forming the tube-like member, the length of longitu-

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dinal slots 2, 3 and by the degree of expansion of the stent-like member 1. An implanted stent-like member 1 has sufficient crush resistance to provide support for a duct or cavity or blood vessel when such duct or cavity or blood vessel exerts a normal radial compressive load on the stent-like member 1 as the result of a major contraction of the duct or cavity or blood vessel. Preferably the stent-like member 1 can be sufficiently robust to support a coronary artery when major contractions are indicated. The implanted stent-like member 1 essentially does not exert a radial load on the duct or cavity or blood vessel it is supporting. The implanted stent-like member 1 allows for a small amount of radial recoverable deflection at low loads as the supported duct or cavity or blood vessel contracts. The low force needed to cause elastically recoverable deflection of stent-like members 1 in response to tissue duct contraction can advantageously minimize irritation to the duct wall when small contractions occur.

Although the invention has been described as useful in an angioplasty procedure, it is understood that the invention is not limited to such a procedure or the use of a stent-like member in a blood vessel. It should be apparent to one skilled in the art that the invention is useful in supporting body tissue in general as well as various blood vessels, e.g., in saphenous vein grafts, the vena cavae, the aorta, the renal artery, the iliac artery, the femoral artery, the popliteal artery, the carotid artery, the cranial arteries, pulmonary arteries, etc. The various embodiments of the invention are also useful with other tubular organs including but not limited to the prostate, biliary tract, the esophagus, the trachea, the fallopian tubes, the vas deferens, the ureters, the tear ducts, the salivary ducts, etc.

According to another embodiment of the invention, a stent-like member is given a memory shape which is larger in size than the lumen of the body organ in which the stent is to be located. According to this embodiment, the stent-like member is conditioned by techniques known to those skilled in the art to memorize a large diameter and the shape memory alloy from which the stent is made has transformation temperatures M_s and A_s above body temperature. In use, the stent-like member is compressed in the martensitic condition to have a smaller diameter when the stent is put on a catheter. Then the stent-like member is introduced through a body organ by means of the catheter and once properly positioned, the stent is mechanically expanded by balloon expansion without plastic deformation of the stent, after which the stent is heated, in vivo, above body temperature to a transition temperature A_s to expand the stent into the austenite condition and thus expand the stent-like member to the memorized larger diameter shape. Subsequently, the stent-like member is allowed to cool to body temperature and return to the martensitic condition. In a preferred embodiment, A_s is above 37° C. and below 62° C. such as 40° to 50° C. and $M_s > 37°$ C.

The stent according to the second embodiment can be used in various ways. For instance, this heat expandable stent can be implanted by partial balloon expansion of the stent followed by complete expansion created by application of heat. The partial balloon expansion would be sufficient to locate the stent at the target site with final expansion aimed at producing a larger final diameter to support the artery. The heat activated final expansion would exert a radial force on the artery wall instantaneously as the stent takes on its austenitic phase when heated to an elevated temperature. This radial force embeds the stent in the artery wall in a controlled way as a result of interaction between the natural resilience of the arterial wall and predetermined final

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expanded diameter of the stent. After the stent is heat expanded, the blood stream rapidly cools the stent into its martensitic phase. As a result, the enhanced ductility of the martensitic phase allows the stent to accommodate variations in the diameter of the artery and provides a fixed stent diameter which does not exert a radial force on the artery, but rather simply acts as a support structure.

The heat expanded stent according to the second embodiment of the invention reduces the barotrauma associated with normal balloon implantation of stents by conventional balloon angioplasty. That is, it is well known that dissections of arterial walls can be caused by expanding balloons and internal trauma can be expected when any mechanical force is applied to the arterial walls. In the case of balloon angioplasty, the total balloon area contacts the inner arterial wall and the trauma is extensive. Furthermore, balloons can protrude through stent structures and extend beyond the ends of stents to give a similar effect. The heat expanded stent according to the second embodiment can avoid the barotrauma problem since it is not necessary to fully expand the stent by balloon expansion. That is, by partial expansion of the stent by using a balloon and final expansion by application of heat there is less contact of the inner arterial wall with foreign bodies such as the stent and balloon than in the case where a stent is fully expanded by balloon expansion. Thus, the heat expanded stent according to the second embodiment can be implanted in a manner which leaves the major area of the stented wall unaffected whereby lower levels of cell proliferation associated with recovery from the trauma and hence less restenosis will occur.

The tissue supporting device according to the claimed invention is non-magnetic and corrosion resistant. Further, the tissue supporting device can include means for making the stent visible and radiopaque under conventional fluoroscopes when in the human body. For instance, the radial wall thickness of the tissue supporting device can be from 0.005 inches to 0.020 inches, thus making the stent visible by radiopaque techniques.

In yet another embodiment of the invention, the stent-like member 1 with shape memory properties can be reversibly manipulated during its manufacture to facilitate secondary processes without affecting the functionality of the final stent-like member 1 product. For example, the original diameter of the stent-like member 1 may be increased to enable the internal surfaces to be mechanically altered by processes such as machining, deburring, etc., and later, the diameter of the stent-like member 1 can be returned to its original dimensions by heating the stent-like member 1 above the transition temperature of the shape memory alloy. By this method, stent-like members with interior surfaces of exceptional machined finish can be obtained in a final stent-like product. In addition, the stent can be surface treated and/or coated with any suitable material such as polymeric material found to be beneficial in providing a surface finish which minimizes thrombogenicity. If desired, the coating could also incorporate additives for drug delivery or other medical purposes.

The stent according to the invention can provide benefits in preventing thrombogenic response. In particular, the stent geometry can be controlled to provide a planar cylindrical profile when expanded with minimal strut twisting and outwardly protruding stent strut terminations. That is, whereas the struts forming the mesh-like structure of stain-

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less steel stents have a tendency to twist such that the edges thereof project radially outwardly when expanded by balloon inflation, the stent according to the invention can be expanded without such twisting of the struts. Further, compared to a stainless steel stent having the same configuration, the stent according to the invention can be expanded at much lower balloon expansion pressures. The lower expansion pressures used in accordance with the invention minimize barotrauma and the smooth outer cylindrical surface of the expanded stent in accordance with the invention provides non-thrombogenic properties.

The foregoing has described the principles, preferred embodiments and modes of operation of the present invention. However, the invention should not be construed as being limited to the particular embodiments discussed. Thus, the above-described embodiments should be regarded as illustrative rather than restrictive, and it should be appreciated that variations may be made in those embodiments by workers skilled in the art without departing from the scope of the present invention as defined by the following claims.

What is claimed is:

1. A method of implanting a permanent tissue supporting device comprising a stent-like member of a shape-memory alloy having martensitic and austenitic metallurgical states and a transition temperature A_s therebetween, the method comprising sequential steps of (i) positioning the stent-like member in a tubular organ of a living body, (ii) mechanically expanding the stent-like member in its martensitic state to form a mechanically expanded shape, (iii) further expanding the stent-like member by heating the mechanically expanded shape above A_s so that the stent-like member is transformed into the austenitic state and recovers a memorized configuration larger than the mechanically expanded shape, and (iv) cooling the stent-like member to body temperature.

2. The method according to claim 1, wherein $37^\circ\text{C} \leq A_s \leq 62^\circ\text{C}$.

3. The method according to claim 1, wherein the mechanically expanding step expands the stent to a size smaller than the inner diameter of the tubular organ.

4. The method according to claim 1, wherein the stent-like member is positioned permanently to support tissue.

5. A method of supporting tissue, comprising the steps of: positioning a permanent generally tubular tissue supporting device in a tubular organ of a living body, the tissue supporting device comprising a shape-memory alloy having martensitic and austenitic metallurgical states and a transition temperature of at least 70°C therebetween; and

permanently fixing the tissue supporting device in the tubular organ such that the tissue supporting device is in the martensitic state, the tissue supporting device exhibiting a strain on a plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the tubular organ.

6. The method according to claim 5, the positioning step comprising crimping the tissue supporting device onto a balloon located at a distal end of a catheter, and navigating the tissue supporting device to an application site within the tubular organ.

7. The method according to claim 6, the fixing step comprising mechanically expanding the tissue supporting device until the balloon is fully expanded.

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EXHIBIT I



US005807404A

United States Patent [19]

Richter

[11] Patent Number: 5,807,404

[45] Date of Patent: Sep. 15, 1998

[54] STENT WITH VARIABLE FEATURES TO OPTIMIZE SUPPORT AND METHOD OF MAKING SUCH STENT

5,575,818 11/1996 Pinchuk 623/1
5,591,197 1/1997 Orth et al. 606/194

FOREIGN PATENT DOCUMENTS

[75] Inventor: Jacob Richter, Ramat Hasharon, Israel

92/06734 4/1992 WIPO 606/194

[73] Assignee: Medinol Ltd., Tel Aviv, Israel

Primary Examiner—Michael J. Milano

Assistant Examiner—Tram Anh T. Nguyen

Attorney, Agent, or Firm—Kenyon & Kenyon

[21] Appl. No.: 716,039

[22] Filed: Sep. 19, 1996

[57] ABSTRACT

[51] Int. Cl.⁶ A61F 2/06

[52] U.S. CL. 623/1

[58] Field of Search 623/1, 11, 12;
606/191, 194, 195

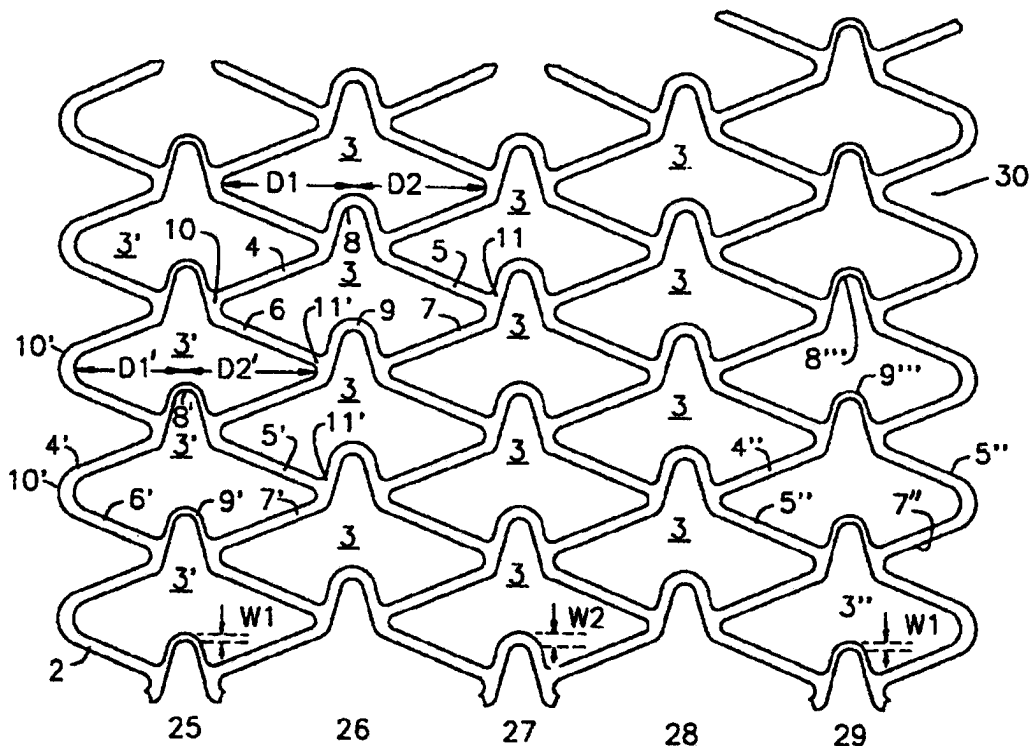
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5,449,373	9/1995	Pinchasik et al.	623/1
5,496,365	3/1996	Sero	606/191
5,514,154	5/1996	Lau et al.	606/144
5,562,697	10/1996	Christiansen	606/191

An intravascular stent especially suited for implanting in curved arterial portions or ostial regions. The stent can include an end region which is fabricated to have a greater radial strength than the remaining axial length of the stent. Such a stent is particularly suited for use in ostial regions, which require greater support near the end of the stent. The stent alternatively can include sections adjacent the end of the stent with greater bending flexibility than the remaining axial length of the stent. Such a stent is particularly suited for use in curved arteries. The stent can also be constructed with an end that has greater radial strength and sections adjacent the end with greater bending flexibility. Such a stent prevents flaring of the stent end during insertion.

28 Claims, 7 Drawing Sheets



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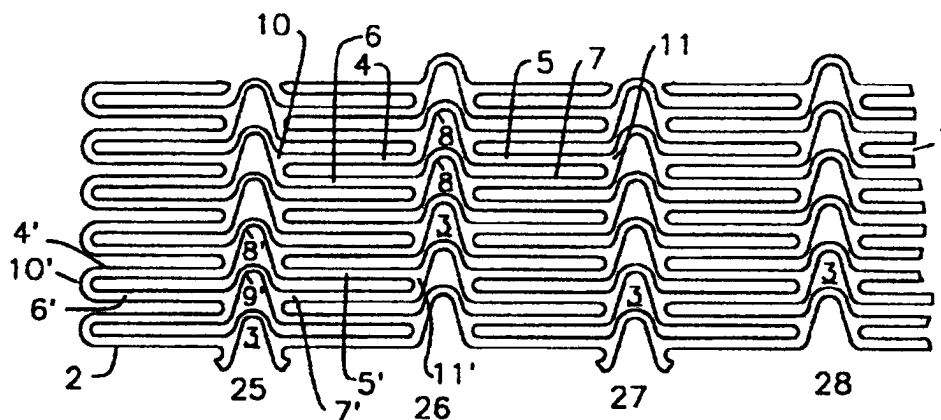


FIG. 1

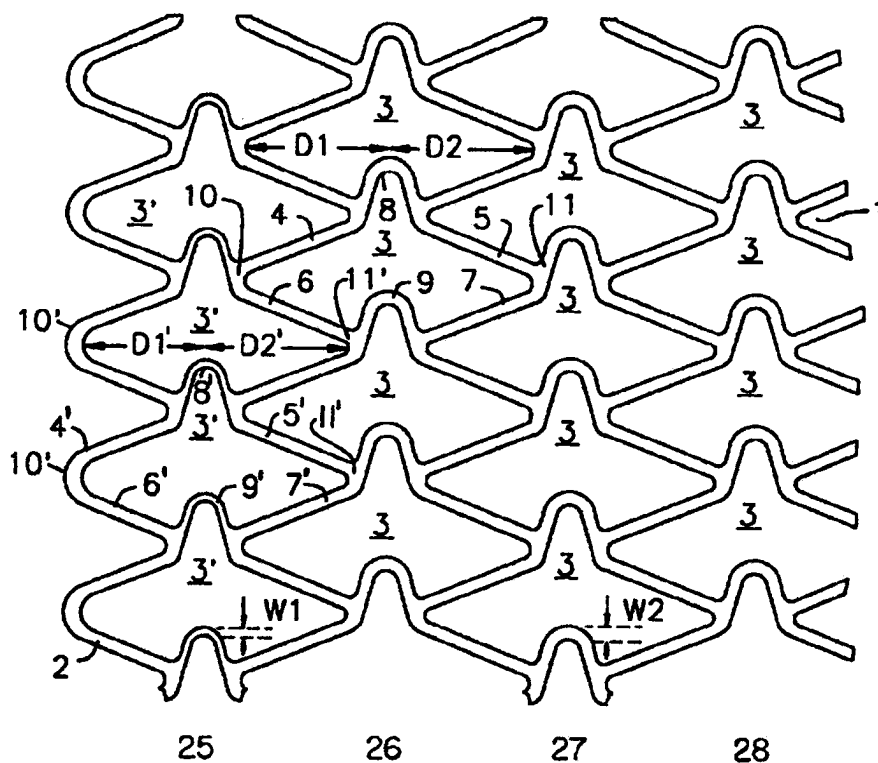


FIG. 2

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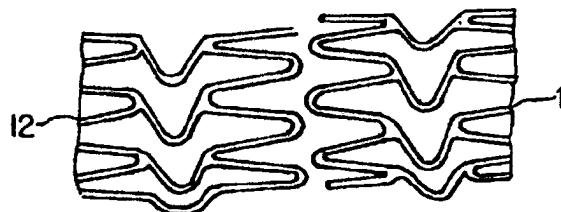


FIG. 3

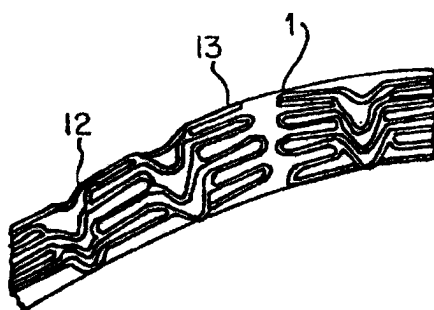


FIG. 4

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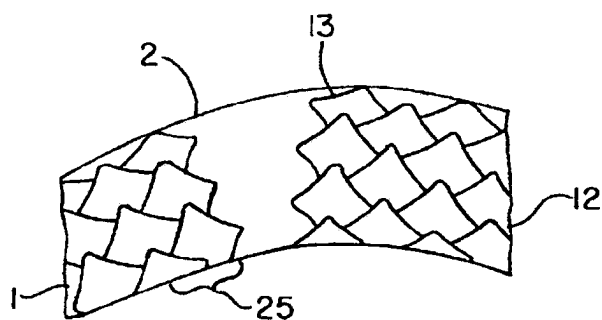


FIG. 5

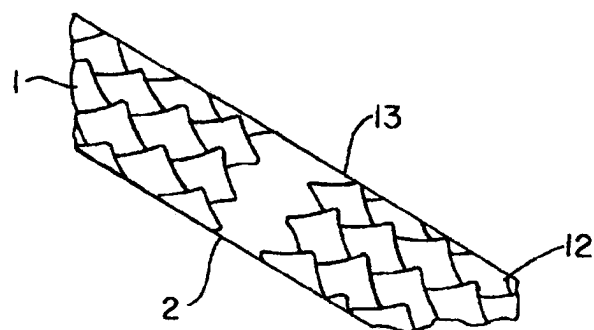


FIG. 6

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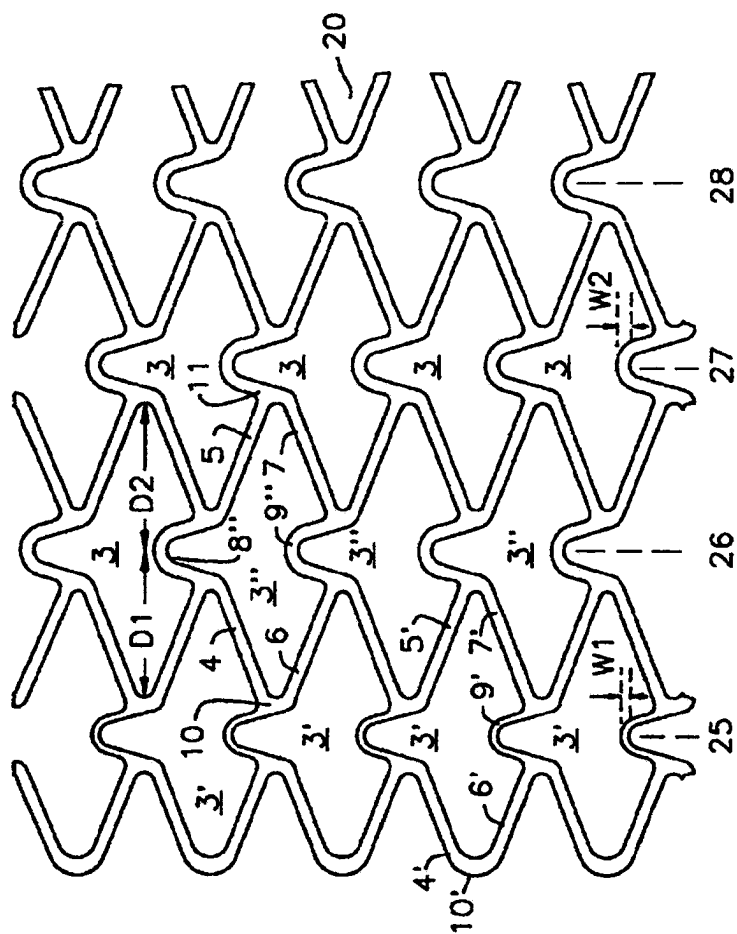


FIG. 7

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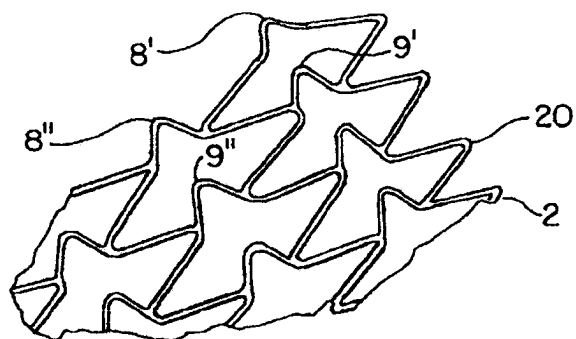


FIG. 8

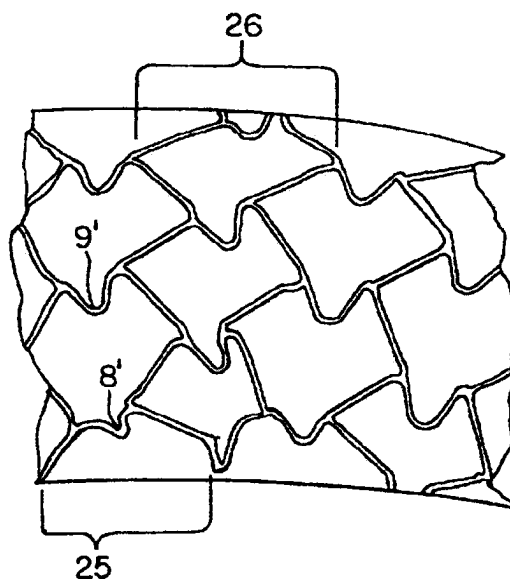


FIG. 9

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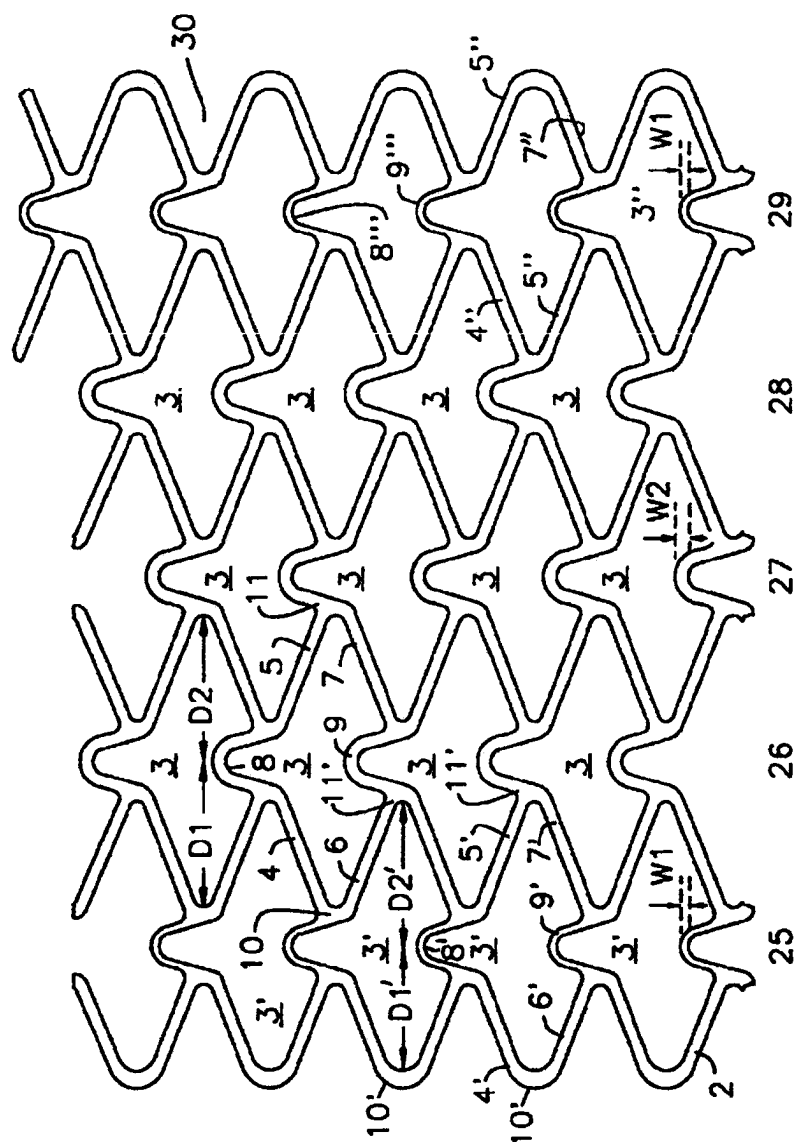


FIG. 10

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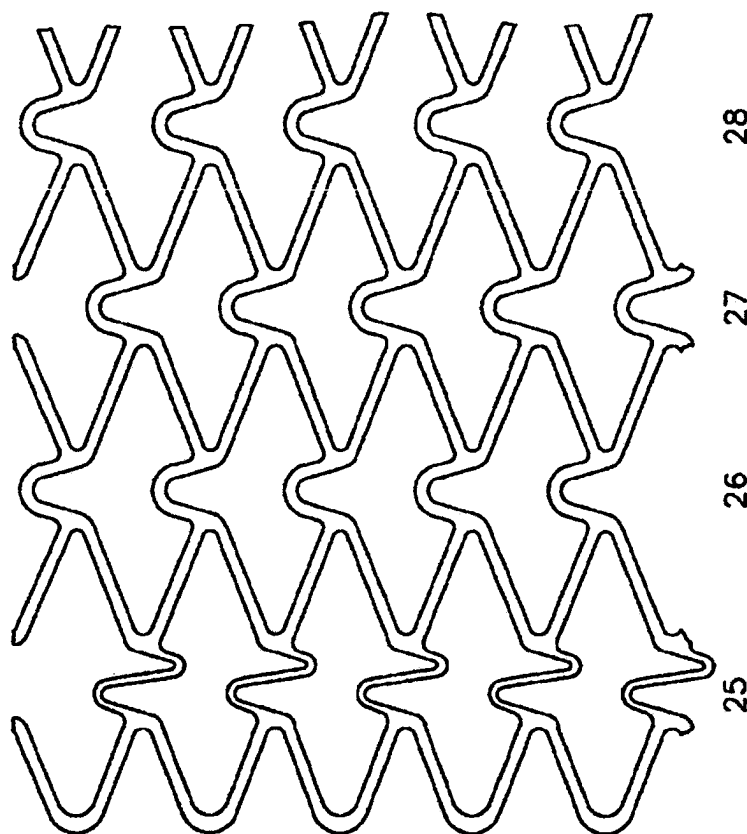


FIG. 11

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STENT WITH VARIABLE FEATURES TO OPTIMIZE SUPPORT AND METHOD OF MAKING SUCH STENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to stents for implanting into a living body. In particular, the present invention relates to intraluminal stents especially suited for implanting in a variety of lumens having variable characteristics, such as variable curvature, side branching, variable diameter, variable wall compliance or "end effects" of either the lumen, as found, e.g., in ostia, or the stent as the parameters may change at its ends.

2. Description of the Prior Art

It is well known to use a stent to expand and impart support to different bodily conduits, such as blood vessels, by expanding a tube-like structure inside the vessel requiring support against collapse or closure. U.S. Pat. No. 5,449,373 shows a stent preferably used for vascular implantation as part of a balloon angioplasty procedure. The stent of U.S. Pat. No. 5,449,373 may be delivered through, or implanted in, a curved vessel. One shortcoming of conventional stents is that they may have deficiencies due to "end effects" where the ends of the stent tend to "flare out" during insertion or after expansion or have a decreased radial force at the end. Still another shortcoming of conventional stents is they do not have different characteristics, (e.g., flexibility and rigidity), to accommodate any changing characteristics of the section of the lumen requiring different stent characteristics.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention provides for various embodiments of an intraluminal stent which includes varied or different mechanical properties along the axial length of the stent in order to improve stent end effects, or to accommodate variable vessel features. As a result, the various embodiments of the present invention allow for variable properties such as flexibility or radial support between axial regions of the stent. These varied properties can be accomplished in a number of different ways, including decreasing or increasing the thickness or width of elements of one or more of the sections relative to other sections and/or increasing or decreasing the axial length of one or more of the sections and/or changing the cell shape and size and/or changing material properties (e.g., strength, elasticity, etc.) of the material in one section relative to other sections.

The various embodiments of the stents of the present invention may be adapted to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted. The degree of flexibility and the distance from the end of the stent to which the extra flexibility is imparted may be varied as specific applications dictate. This flexibility at the ends reduces the chance of a potential trauma point being created in the vessel by the stent tip pressing on the wall outside of the curve if the stent is not flexible enough along its longitudinal axis. In one embodiment of the present invention, flexibility of the stent ends is increased by reducing the gauge of the material used in a section or sections at the stent ends. In another embodiment the flexibility of the stent ends is increased by changing the dimensions of a section or sections at the stent ends. In yet another embodiment of the invention, the flexibility of the stent ends is increased by changing both the

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dimensions and the gauge of the material used in a section or sections at the stent ends.

The various embodiments of the stents of the present invention may also be adapted to insure increased radial strength at the ends. Radial strength is the resistance of a section of the stent, in an expanded state, to radial contraction. Increasing the radial strength of a stent at the ends is particularly advantageous for stents supporting ostia. Because lesions at an ostium tend to be more calcified or hardened, and therefore require more support, the section of the stent supporting the ostium must be relatively strong. It is also the case that a stent with uniform characteristics has a decreased radial force at the end due to the "end effect" whereby the last row has no support on one side. In one embodiment of the present invention, the strength of the stent at the end supporting, e.g., the ostium, is increased by reducing the length of some sections at the stent end.

The various embodiments of the stent of the present invention also reduce the chance of "flare" at the end of the stent while the stent is being fed into a vessel. During insertion of the catheter delivery system into a curved vessel, the delivery system, including the stent crimped on it, bend along the curvature of the vessel. This bending of the stent can cause a "flaring out" of the leading edge of the stent. This flaring could cause the stent to catch on the surface of the vessel which could result in trauma to the vessel, could inhibit further insertion and proper positioning in the target area, and could cause plaque to break off, which could embolize and clog the vessel. In one embodiment of the present invention, flare is minimized by making the section at the stent end stronger by reducing its length, and by making sections adjacent to the stent end more flexible by reducing their widths, thus, decreasing the bending strength of those sections. Bending strength is the resistance of a section of the stent to axial bending. As a result, the end of the stent remains tightly crimped on the balloon, and the bending moment is taken up by the deformation of the more flexible sections. Upon expansion, the reduced bending strength allows the end of the stent to curve and fit better the curvature of the vessel, thereby, reducing the pressure of the tip of the stent on the internal wall of the vessel being treated.

It is an object of this invention to provide a stent which does not have sharp points or protrusions at its end concentrating pressure on the vessel's wall upon expansion of the stent in a curved portion of a vessel.

It is another object of this invention to provide a stent having a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells disposed in the distal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal end of the stent.

It is still another object of this invention to provide an expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a

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plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of said stent and a proximal row disposed at the proximal end of the stent, wherein the cells in the distal row of the stent and the cells disposed in the proximal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal row.

It is another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a longitudinal stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row, and the row proximal to the distal row, are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is a further aspect of this invention to provide an expandable stent comprising: a) a plurality of flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of flexible rows along the longitudinal axis with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that

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are shorter than the second and fourth members in the distal row, and wherein the cells of the proximal row are provided with second and fourth members that are shorter than the first and third members in the proximal row, and wherein the distal row, and the row proximal to the distal row, and the proximal row and the row distal to the proximal row are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet a further object of this invention to provide an expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its proximal and distal ends that is greater than the radial force of that portion of the stent disposed between the proximal and distal ends.

It is another object of this invention to provide an expandable stent for treating a lumen having a unique characteristic along a portion of the lumen, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the unique characteristic of that portion of the lumen in contact with the adapted row or rows.

It is yet another object of this invention to provide a single flexible stent with a unibody or one-piece construction which is capable of imparting support to a lumen or vessel along the entire length of the stent and in which portions of the stent are adapted or modified so as to have characteristics, e.g., bending strength or radial strength, that are different than the characteristics or features in the rest of the stent along its longitudinal axis or about its circumference. The change in stent features will either accommodate non-uniformity in the treated lumen or may create different environmental conditions in different areas in the lumen. Non-uniformity in a treated vessel can be of many different types such as an ostium, change in diameter, change in curvature, non-continuous cross-section such as triangular or square, or non-uniformity in surface nature, etc. To accommodate such non-uniformity, portions of the stent may be adapted to provide changing dimension, flexibility, rigidity, size of cells, shape of cells, and response to pressure as dictated by specific applications. Specific applications may dictate, e.g., a desired higher radial force at one end while the other portions of the stent provide a substantially continuous support to the vessel wall with the gaps in the stent sized small enough to reduce the likelihood of tissue prolapse. Other applications may dictate a desired degree of stiffness in the center to reduce the likelihood of breakage and impart the desired degree of softness at the end to allow for the best fit with the anatomy of the target area. Other applications may dictate that one or more of the rows be provided with cells that are sized larger than the cells in the remaining rows of the stent so as to provide access to a side branch in the lumen, e.g., for introducing a second stent through one of the larger sized cells so as to permit construction of a bifurcated stent within the lumen. Still another application may dictate that one or more of the rows be provided with cells which are adapted or modified so that upon expansion of the stent the portion of the stent defined

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by the adapted or modified row or rows has a diameter that is either larger or smaller than the remaining portions of the stent to accommodate lumens with non-uniform diameters. One or more rows of cells may also be adapted or modified so as to have varying radial force, or varying longitudinal flexibility, or to correct for a change in properties at the end of the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an illustration of the basic pattern of an embodiment of the stent of the present invention, shown in an unexpanded state;

FIG. 2 shows an illustration of the pattern of the stent of FIG. 1, in a partially expanded state;

FIG. 3 is a side view showing a conventional stent and a stent manufactured in accordance with one embodiment of the invention;

FIG. 4 shows the stents of FIG. 3 crimped on a balloon catheter and bent prior to expansion;

FIG. 5 shows the stents of FIG. 4 after they have been expanded in a curve;

FIG. 6 shows the stents of FIG. 3 partially expanded on a substantially straight balloon catheter;

FIG. 7 shows an alternative embodiment of the invention provided with a shortened C-shaped loop and in which two rows of cells are provided with thinner gauge U-shaped loops;

FIG. 8 shows the stent of FIG. 7 partially expanded on a substantially straight balloon catheter;

FIG. 9 shows the stent of FIG. 7 after it has been expanded on a curved catheter as it would be when inserted around a bend in a vessel;

FIG. 10 shows an alternative embodiment of a stent constructed in accordance with the invention; and

FIG. 11 shows the "S" or "Z" shaped loops constructed in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows the general configuration of one embodiment of a stent 1 fabricated in accordance with the present invention. The stent 1 may be fabricated of bio-compatible materials such as stainless steel 316L, gold, tantalum, nitinol or other materials well known to those skilled in the art as suitable for this purpose. The dimensions and gauge of material utilized may be varied as specific applications dictate. The stents of the present invention generally may be constructed in a manner in accordance with the stent described in U.S. patent application Ser. No. 08/457,354, filed Jun. 1, 1995, the disclosure of which is incorporated herein by reference.

FIG. 1 is a side view of the distal end 2 of stent 1 of the present invention, showing the general pattern of the stent. As shown in FIGS. 1 and 2 the pattern may be described as a plurality of cells 3 and 3'. Each cell 3 is provided with a first member 4, a second member 5, a third member 6, and a fourth member 7. A first C-shaped loop 10 is disposed between the first member 4 and the third member 6 and a second C-shaped loop 11 is disposed between the second member 5 and the fourth member 7. In each of the cells 3, first member 4, second member 5, third member 6, and fourth member 7 are substantially equal. Thus, first C-shaped loop 10 is displaced a distance D1 and second C-shaped loop 11 is displaced a distance D2 from the center

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of cell 3. In a preferred embodiment, D1 is substantially equal to D2. A first flexible connector 8 is disposed between the first member 4 and the second member 5 and a second flexible connector 9 is disposed between third member 6 and fourth member 7. The flexible connectors 8 and 9 may be made in a variety of shapes, e.g., an "S" or a "Z" shape as shown in FIG. 11. In a preferred embodiment, a "U" shape is utilized as shown in FIGS. 1 to 10.

FIG. 1 shows the pattern of stent 1 in an unexpanded state, i.e., that state in which the stent 1 is first inserted in a particular vessel in which a balloon angioplasty procedure is to be performed, but before balloon inflation. FIG. 2 shows the pattern of stent 1 in a partially expanded state, i.e., that state after the balloon has been expanded, e.g. by a balloon, and the state in which the stent 1 remains in the vessel which it supports. The plurality of interconnected cells 3 and 3' form a plurality of interconnected rows 25, 26, 27, and 28 of cells disposed along the longitudinal axis of the stent 1. FIGS. 1 and 2 show a distal row 25 disposed at the distal end 2, a row 26 adjacent to and proximal to distal row 25, a row 27 adjacent to and proximal to row 26, and a row 28 adjacent to and proximal to row 27. It will be appreciated that the number of rows, and the number of cells per row, and the shape of each cell, may be varied as specific applications require.

As shown in FIGS. 1 and 2, the cells 3' in distal row 25 differ from the cells 3 in rows 26, 27, and 28. The first member 4' and the third member 6' of the cells 3' in row 25 are shorter than the first member 4 and the third member 6 of the cells 3 in rows 26, 27 and 28. In cell 3', first member 4' is substantially equal to third member 6', however, first member 4' and third member 6' are shorter than second member 5' and fourth member 7'. The shorter members 4' and 6' result in a first C-shaped loop 10' that is not disposed as far away from the center of the cell 3' as second C-shaped loop 11'. Thus, first C-shaped loop 10' may be thought of as being "shorter" than second C-shaped loop 11'. As shown in FIG. 2, first C-shaped loop 10' is disposed a distance D1' that is less than the distance D2' that second C-shaped loop 11' is disposed from the center of the cell 3'. In an especially preferred embodiment, D1' is about 15% less than D2'.

FIGS. 1 and 2 also show that the distal row 25 of the stent 1 is provided with a first U-shaped loop 8' and a second U-shaped loop 9' that are more flexible than the first U-shaped loop 8 and second U-shaped loop 9 of cells 3 in rows 26, 27, and 28 of the stent 1. This greater flexibility in the U-shaped loops 8' and 9' may be accomplished in a variety of ways, for example, by utilizing a different material, by treating the material e.g., by utilizing stainless steel annealing to impart selective degrees of hardness to the different portions of the stent. Alternatively, if, e.g., NiTi (Nitinol) is utilized, selected portions of the stent may be selectively thermo-mechanically treated so that portions of the stent, e.g., the U-shaped members, will remain in a martensitic phase while other portions of the stent will be transformed into austenitic phase in this section to yield different properties. Greater flexibility may also be achieved by changing the shape of the "U", for example to a "Z" or an "S" (as shown in FIG. 11), or by reducing the amount of material utilized to make the U-shaped loops 8' and 9'. In the embodiment shown in FIGS. 1 and 2, the U-shaped loops 8' and 9' of row 25 are provided with the same thickness of material as the U-shaped loops 8 and 9 of the cells 3 in rows 26, 27, and 28, however, U-shaped loops 8' and 9' are not as wide. As shown in FIGS. 1 and 2, U-shaped loops 8' and 9' have a width W1 that is less than the width W2 of U-shaped loops 8 and 9 in the cells 3 of rows 26, 27, and 28. In a

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preferred embodiment, W1 is about 50% narrower than W2. In an especially preferred embodiment, W1 is about 40% narrower than W2.

FIG. 3 is a side-by-side comparison of two stent sections and shows a conventional stent 12 compared to the stent 1, shown in FIGS. 1 and 2. FIG. 4 shows stents 1 and 12 shown in FIG. 3 as they appear when they are crimped on a balloon and bent as they would be during insertion around a curve in a vessel. As shown in FIG. 4, conventional stent 12 flares at its leading edge 13 in contrast to stent 1 which does not. FIG. 5 shows the stents of FIG. 4 after the stents have been expanded in a curve. The tip of conventional stent 12 produces a protrusion or sharp point 13 which could cause local pressure and possible trauma to the vessel wall. In contrast, the stent 1 constructed in accordance with the invention bends gently at its end 2 without forming a protrusion or sharp point because the deformation of the of U-shaped loops 8' and 9' in distal row 25 make the end 2 softer.

FIG. 6 shows the stents 1 and 12 of FIG. 3 at partial expansion (before reaching maximum pressure) disposed on a substantially straight catheter. As shown, although the two stents 1 and 12 are subjected to the same outward force, the end 2 of stent 1 is less expanded than the end 13 of conventional stent 12 demonstrating the increased radial force of the end 2 of stent 1 constructed in accordance with the invention. At full pressure the radii of the stents 1 and 12 will be equal, however, the end 2 of stent 1 will have greater radial resistance to collapse than the end 13 of stent 12.

FIG. 7 shows an alternative embodiment of the invention. As shown in FIG. 7, the cells 3' in row 25 are provided with a first member 4' and third member 6' that are shorter than second member 5' and fourth member 7'. The cells 3' in row 25 are provided with a first U-shaped loop 8' and a second U-shaped loop 9' that are thinner than the U-shaped loops 8 and 9 in the cells 3 in rows 27 and 28. The cells 3' in row 26 are provided with first U-shaped loops 81" and second U-shaped loops 9" that are narrower than the U-shaped loops 8 and 9 in the cells 3 in rows 27 and 28.

FIG. 8 shows the stent 20 of FIG. 7 during partial expansion of the stent showing the decreased expansion of row 25 at partial expansion because of the higher radial force of the end 2 of the stent which results from construction with shorter C-shaped loops 10' in row 25, construction with narrower, i.e., more flexible, U-shaped loops 8' and 9' in row 25, and 8" and 9" in row 26.

FIG. 9 shows the stent 20 of FIGS. 7 and 8 after it has been expanded in a curved vessel and shows the bends of the U-shaped loops 8' and 9' in row 25 and 8" and 9" in row 26 which allows the end portion 2 of the stent 20 to more readily conform to the curve of the vessel, creating smooth ends with no sharp points or projections projecting into the vessel wall.

The changes can be made on one side only or on both sides of the stent as specific applications dictate. Additionally, different combinations of embodiments of the invention may be mixed such as using thinner U-shaped loops, longer U-shaped loops or different shaped loops, e.g., "Z" or "S".

One example of how this may be achieved is shown in FIG. 10. FIG. 10 shows how the stent shown in FIG. 7 may be modified, if additional flexibility is desired. As shown in FIG. 10, the distal row 25, and the proximal row 29 of stent 30 are provided with first and second U-shaped loops that are more flexible than the U-shaped loops in the other rows of the stent disposed between the distal and proximal rows

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25 and 29. In the embodiment of the invention shown in FIG. 10, the distal row 25 is provided with shortened members 4' and 6' and more flexible U-shaped loops 8' and 9', as previously discussed, and the proximal row 29 is provided with shortened second and fourth members 5" and 7" and more flexible U-shaped loops 8" and 9". This arrangement imparts greater radial strength and greater flexibility to both ends of the stent.

If even greater flexibility at the ends of the stent is desired, the stent shown in FIG. 10 may be modified by replacing the U-shaped loops in rows 26 and 28 with more flexible loops. Thus, the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row are provided with U-shaped loops that are more flexible than the U-shaped loops in the cells in the remaining rows of the stent.

The present invention contemplates a number of different variations and changes in different properties to achieve other non uniform features such as, but not limited to, cell size, cell shape, radio-opacity, etc. on the above-described preferred embodiments. The specified changes are brought only as an example for the application of the general concept, which is the basis for the present invention that stents with varying mechanical properties between sections along the stent may correct undesired effects at singular points such as stent ends and provide for a better fit to a vessel with properties changing along its axis. It is to be understood that the above description is only of one preferred embodiment, and that the scope of the invention is to be measured by the claims as set forth below.

What is claimed is:

1. An expandable stent, comprising:

- a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;
- b) a first C-shaped loop disposed between the first member and the third member;
- c) a second C-shaped loop disposed between the second member and the fourth member;
- d) a first flexible connector disposed between the first member and the second member; and
- e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent;

wherein the first and the second flexible connectors in the distal row are narrower than the first and the second flexible connectors in the cells in the rows other than the distal row of the stent.

2. The stent of claim 1, wherein the first and the second flexible connectors in the distal row are about 40 narrower than the first and the second flexible connectors in the cells in the rows other than the distal row of the stent.

3. An expandable stent, comprising:

- a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of

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interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent;

wherein the first and the second flexible connectors in the distal row are annealed to impart a hardness that is different than the hardness of the flexible connectors in the rows other than the distal row of the stent.

4. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent;

wherein the stent is comprised of NiTi having an austenitic and martensitic phase and the first and the second flexible connectors in the distal row of the stent are in a martensitic phase and the portions of the stent other than the first and the second flexible connectors in the distal row are in the austenitic phase.

5. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

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d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent;

wherein the cells in the distal row are of a thinner gauge than the gauge of the material utilized in the cells not disposed in the distal row of the stent.

6. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent;

wherein the cells in the distal row are made of a material that is more flexible than the material utilized in the cells not disposed in the distal row of the stent.

7. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a longitudinal stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row, and in the row adjacent to the distal row, are provided with first and second flexible connectors that are more flexible than the flexible connectors in the rows other than the distal row and the row adjacent to the distal row of the stent.

8. The stent of claim 7, wherein the first and the second flexible connectors are U-shaped.

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9. The stent of claim 7, wherein the first and the second flexible connectors are S-shaped.

10. The stent of claim 7, wherein the first and the second flexible connectors are Z-shaped.

11. The stent of claim 7, wherein the first and the third members in the distal row are about 15% shorter than the second and the fourth members in the distal row.

12. The stent of claim 7, wherein the first and the second flexible connectors in the distal row and in the row adjacent to the distal row are narrower than the first and second flexible connectors in the cells in the rows other than the distal row and the row adjacent to the distal row of the stent.

13. The stent of claim 12, wherein the first and the second flexible connectors in the distal row and in the row adjacent to the distal row are about 40% narrower than the flexible connectors in the cells in the rows other than the distal row and the row adjacent to the distal row of the stent.

14. The stent of claim 7, wherein the first and the second flexible connectors in the distal row and in the row adjacent to the distal row are annealed to impart a hardness that is different from the hardness of the flexible connectors in the rows other than the distal row and the row adjacent to the distal row of the stent.

15. The stent of claim 7, wherein the stent is comprised of NiTi having an austenitic and martensitic phase and the first and the second flexible connectors in the distal row and the row adjacent to the distal row are in a martensitic phase and the portions of the stent other than the first and second flexible connectors in the distal row and the row adjacent to the distal row are in the austenitic phase.

16. The stent of claim 7, wherein the cells in the distal row and in the row adjacent to the distal row are of a thinner gauge than the gauge of the material utilized in the cells disposed in the rows of the stent other than the distal row and the row adjacent to the distal row.

17. The stent of claim 7, wherein the cells in the distal row and the row adjacent to the distal row are made of a material that is more flexible than the material utilized in the cells disposed in the rows of the stent other than the distal row and the row adjacent to the distal row.

18. An expandable stent comprising:

a) a plurality of flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of flexible rows along the longitudinal axis with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member;

b) a first C-shaped loop disposed between the first member and the third member;

c) a second C-shaped loop disposed between the second member and the fourth member;

d) a first flexible connector disposed between the first member and the second member; and

e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the cells of the proximal row are provided with second and fourth members that are shorter than the first and third members in the proximal row, and wherein the distal row, and the row adjacent to the distal row, and the proximal row and the row adjacent to the proximal row are provided with first and second flexible connectors that are more flexible than the flexible connectors in the rows of the stent

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other than the distal row and the row adjacent to the distal row and the proximal row and the row adjacent to the proximal row.

19. The stent of claim 18, wherein the first and the second flexible connectors are U-shaped.

20. The stent of claim 18, wherein the first and the second flexible connectors are S-shaped.

21. The stent of claim 18, wherein the first and the second flexible connectors are Z-shaped.

22. The stent of claim 18, wherein the first and the second flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are narrower than the first and the second flexible connectors in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

23. The stent of claim 18, wherein the first and the second flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are narrower than the first and the second flexible connectors in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

24. The stent of claim 23, wherein the first and the second flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are about 40% narrower than the first and the second flexible connectors in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

25. The stent of claim 7, wherein the flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are annealed to impart a hardness that is different from the hardness of the first and the second flexible connectors in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

26. The stent of claim 7, wherein the stent is comprised of NiTi having an austenitic and martensitic phase and the first and the second flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are in a martensitic phase and the portions of the stent other than the first and the second flexible connectors in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are in the austenitic phase.

27. The stent of claim 18, wherein the cells in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row are of a thinner gauge than the gauge of the material utilized in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

28. The stent of claim 18, wherein the cells in the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row of the stent are made of a material that is more flexible than the material utilized in the cells disposed in the rows of the stent other than the distal row, the row adjacent to the distal row, the proximal row, and the row adjacent to the proximal row.

* * * * *

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO. :5,807,404

DATED :September 15,1998

INVENTOR(S) :Jacob Richter

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page

"Foreign Patent Documents" insert

--	96/26689	8/1996	WIPO
	97/40781	11/1997	WIPO
	95/31945	11/1995	WIPO
	0 541 443	5/1993	EP
	0 800 801	10/1997	EP --

Signed and Sealed this

Twenty-fifth Day of May, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks

EXHIBIT J

D.I. 407

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Defendants.

C.A. No. 03-027-SLR

**BSC'S OPPOSITION TO CORDIS' RENEWED MOTION FOR JMOL
OR, IN THE ALTERNATIVE, A NEW TRIAL ON THE JANG '021 PATENT**

YOUNG CONAWAY
STARGATT & TAYLOR, LLP
Josy W. Ingersoll (I.D. #1088)
John W. Shaw (I.D. #3362)
Karen E. Keller (I.D. #4489)
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, Delaware 19899
(302) 571-6600

*Attorneys for
Boston Scientific Corporation
and Boston Scientific Scimed, Inc.*

Of Counsel:

John M. Desmarais
Peter J. Armenio
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, New York 10022-4611
(212) 446-4800

Dated: September 26, 2005

different manners" and that "[a]ll of these variations of the connecting patterns . . . are within the scope of the present invention." (BSE 3402 at JFH 000026) This testimony was substantial evidence that supports a finding of a 1996 priority date.

Cordis argues that Claim 36 is not entitled to the benefit of the 1996 filing date because "[t]here is no disclosure of a 'bottom-to-top connection'" in the provisional application, only "bottom-to-bottom and top-to-top connectors." (COB at 27) But this argument is misguided for a number of reasons. First, Claim 36, as properly construed, is directed to a stent having curvy, *offset* connectors. And these connectors are disclosed in the provisional application.

For example, the provisional application describes the concept of "split level" connectors, connectors which have ends that are not circumstantially aligned. (*See, e.g.*, BSE 3402 at JFH 000011) The figures illustrate multiple possible embodiments of that invention (*see id.* at JFH 000033-40), and the text nowhere limits the invention to "bottom-to-bottom," "top-to-top" or "bottom-to-top" connectors. Indeed, those terms are nowhere to be found in either the provisional application or the '021 patent. Rather, as discussed above, the provisional application discloses the invention of a stent having expansion columns that are connected by curvy, offset connectors and that numerous "variations of the connecting patterns . . . are within the scope of the present invention." (*Id.* at JFH 000026)

Second, contrary to Cordis' suggestion, an exact depiction of the subject matter of Claim 36 is not required. *See, e.g., Koito Mfg. Co. v. Turn Key Tech., LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004) ("Terms need not be used in haec verba Instead, we have explained that the written description requirement can be satisfied by 'words, structures, figures, diagrams, formulas, etc.'" (citations omitted)). *Lockwood v. American Airlines, Inc.*, relied upon by Cordis, explains that "the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art." 107 F.3d 1565, 1572 (Fed. Cir. 1997). That is exactly what Dr. Moore did at trial. Consistent with Dr. Moore's testimony, one of skill in the art would recognize the subject matter of Claim 36 from reading the provisional application based upon: (1) the disclosure of a stent having "split level" or offset connecting struts; (2) the drawings illustrating examples of these "split level" connecting struts; and (3)

EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,

Plaintiff,

- against -

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Defendants.

C.A. No. 03-027-SLR

**REPLY BRIEF IN SUPPORT OF CORDIS' MOTION FOR JMOL OR,
IN THE ALTERNATIVE, A NEW TRIAL ON INFRINGEMENT OF
THE JANG '021 PATENT UNDER THE CLAIM CONSTRUCTION
THAT BSC SUCCESSFULLY ADVOCATED IN ANOTHER COURT**

Of Counsel:

PATTERSON BELKNAP WEBB & TYLER LLP
Gregory L. Diskant
Eugene M. Gelernter
Kathleen M. Crotty
Ravi V. Sitwala
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue, 8th Floor
Wilmington, DE 19899
(302) 654-1888

Attorneys for Cordis Corporation

Dated: April 17, 2007

"offset" expansion strut pairs is what "allowed us [BSC] to win the judgment we did [in Delaware] against J&J" *Id.*

- In this case, BSC asserts "Cordis is actually asking this Court to adopt a new claim construction that was never proposed ... in the California court." (D.I. 430 at 1). Yet, in California BSC proposed precisely the claim construction that Cordis is now seeking – and it won the case when it succeeded in obtaining that construction.
- In this case, BSC tells this Court that the "issue of overlap" between the columns formed by the expansion strut pairs and the columns formed by the connecting struts, was "never raised" in the California action. D.I. 430 at 8. Yet BSC relied on that precise argument in the California case, asserting that the claim construction needs to "make sure that an expansion strut column and a connecting strut column ... are not overlapping." Ex. H at Tr. 88:21-23.

As these examples demonstrate, BSC is willing to speak out of both sides of its mouth in these two federal courts, taking whatever position, and making whatever representation, will serve its interests at the moment, no matter how great the contradiction between what it tells this Court and the court in California. Courts understandably have no tolerance for this kind of judicial gamesmanship. *See Transclean*, 474 F.3d at 1307 (applying judicial estoppel).

D. Cordis Could Not Have Sought Relief Based on the Claim Construction from the California Case Before BSC Advocated and Obtained that Construction

Last but not least, BSC argues that Cordis should have raised the issues presented by this motion in 2004-05. That might make sense if BSC had advocated or obtained its claim

EXHIBIT L

Conor Medsystems, Inc.

ACTION AUTHORIZED BY
UNANIMOUS CONSENT OF DIRECTORS
IN LIEU OF A
SPECIAL MEETING OF DIRECTORS

The undersigned, being all of the duly elected Directors of Conor Medsystems, Inc., a Delaware corporation, pursuant to the provisions of Delaware General Corporation Law, Section 141 (f), do hereby authorize and consent to the following action being taken in lieu of a Special Meeting of Directors:

RESOLVED: that Cordis Corporation is not and shall not be authorized to act as the legal representative or agent for Conor Medsystems, Inc. in any capacity whatsoever, and further

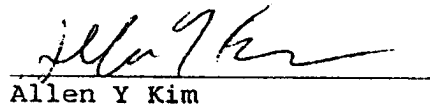
RESOLVED: that Conor Medsystems, Inc. shall not act as nor shall it be deemed to be the legal representative or agent for Cordis Corporation in any capacity whatsoever.



Laurence S Rickles



James J Bergin



Allen Y Kim

Effective Date: February 1, 2007

EXHIBIT M

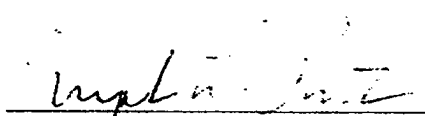
Cordis Corporation

ACTION AUTHORIZED BY
UNANIMOUS CONSENT OF DIRECTORS
IN LIEU OF A
SPECIAL MEETING OF DIRECTORS

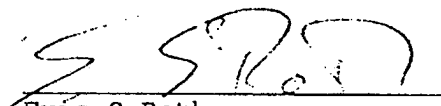
The undersigned, being all of the duly elected Directors of Cordis Corporation, a Florida corporation, pursuant to the provisions of Florida General Corporation Act, Section 607.0821, do hereby authorize and consent to the following action being taken in lieu of a Special Meeting of Directors:

RESOLVED: that Conor Medsystems, Inc. is not and shall not be authorized to act as the legal representative or agent for Cordis Corporation in any capacity whatsoever, and

FURTHER RESOLVED, that Cordis Corporation shall not act as nor shall it be deemed to be the legal representative or agent for Conor Medsystems, Inc. in any capacity whatsoever.



Joseph L Prati



Eric S Roth

Effective Date: February 1, 2007